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No. ___

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade.

2. Whether the court of appeals grossly misapplied the pertinent "substantial evidence" standard of review, by summarily rejecting the extensive factual findings of an expert federal agency regarding matters within its purview.

PARTIES TO THE PROCEEDING

Petitioner is the Federal Trade Commission. Respondents, who were petitioners in the court of appeals below, are Schering-Plough Corporation, and Upsher-Smith Laboratories, Inc.

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PETITION FOR A WRIT OF CERTIORARI

The Federal Trade Commission, pursuant to the authority of 15 U.S.C. 56(a)(3)(A), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.[1]

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[1] The Commission has exercised its authority to represent itself before this Court only twice previously, in the 30 years that it has had that authority. See Pub. L. No. 93-637, § 204(a), 88 Stat. 2183, 2199-2200 (1975); *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447 (1986) ("*IFD*"); *FTC* v. *Superior Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990). The Commission takes this step now not only to seek correction of a ruling that conflicts with fundamental antitrust and administrative law principles, but because of the great urgency of the matter, in light of the billions of dollars of consumer savings on prescription drugs that the ruling below jeopardizes. See *infra* at 24-26.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 402 F.3d 1056. The order of the court of appeals denying rehearing and rehearing *en banc* (Pet. App. 341a-342a) is unreported. The Opinion of the Commission and Final Order (Pet App. 36a-153a) will be reported at 136 F.T.C. ___. The Initial Decision of the Administrative Law Judge (Pet. App. 154a-340a) will be reported at 136 F.T.C. ___.

JURISDICTION

The judgment of the court of appeals was entered on March 8, 2005. A petition for rehearing was denied on May 31, 2005. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. 1; the Federal Trade Commission Act, 15 U.S.C. 45; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet. App. 343a-363a.

STATEMENT

In the Hatch-Waxman Act, Congress sought to speed the entry of low-cost generic drugs into the market by encouraging challenges to patent claims that stand impermissibly in the way of entry. The Act has been remarkably successful; generic challengers have prevailed in most cases in which courts have

ruled on arguments that drug patents were either invalid or not infringed by the challengers, and American consumers have saved billions of dollars as a result.

The present case involves a stratagem that a number of pharmaceutical companies have used to frustrate Congress's resolve to subject drug patents to scrutiny, by entering into agreements that allow them to delay the entry of generic drugs and share the profits derived from maintaining high drug prices. In the two agreements at issue here, the generic manufacturers agreed to delay sale of their products until specified future dates in exchange for cash payments from the patentee. Because the parties anticipated that the patentee's enhanced profits from delayed generic competition would far exceed the generic competitors' lost profits, the parties could share a windfall, at the expense of consumers. Petitioner Federal Trade Commission ("Commission") applied well settled antitrust principles to rule that those agreements unreasonably restrained trade by foreclosing the possibility of earlier generic entry, but the court of appeals set aside the Commission's decision on the ground that any competition forgone was within the "exclusionary potential" of the patent claims, regardless of the purpose or effect of the agreements. Pet. App. 17a. By protecting agreements in which patentees buy off potential challengers from effective antitrust challenge, the ruling below conflicts with fundamental antitrust principles and threatens to vitiate an important statute designed to promote the health and economic well-being of American consumers. The ruling comes at a crucial point. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, are currently subject to litigation by generics seeking to enter the market. See note 23, *infra*.

1. Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims. H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984). The Act allows for

accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing that the new drug is "bioequivalent" to an approved drug. 21 U.S.C. 355(j). It also encourages the development of generic drugs by declaring various research and development activities non-infringing. 35 U.S.C. 271(e)(1); see *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

The Act's incentive structure to accelerate the introduction of generic drugs begins with the requirement that the branded firm submit to the FDA a list of all patents that the firm claims cover its drug. 21 U.S.C. 355(b)(1). A generic firm submitting an ANDA must make a certification regarding the application of any listed patent to its product. Most pertinent here, a so-called "Paragraph IV certification" states that the patent is invalid or not infringed, and thus clearly identifies a patent dispute. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Congress sought to encourage patent challenges by providing that the first generic applicant filing a Paragraph IV certification would obtain 180 days of marketing exclusivity. 21 U.S.C. 355(j)(5)(B)(iv). No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent. Congress likewise created an economic incentive for the patent holder to commence suit upon receiving a Paragraph IV notification. Upon receipt of notice from an ANDA filer, the patent holder receives an automatic 30-month stay prohibiting generic entry into the market, if it sues the generic for infringement within 45 days. 21 U.S.C. 355(j)(5)(B)(iii). If such litigation is not commenced within 45 days, however, the FDA approval process may proceed, and the FDA may approve the ANDA as soon as regulatory requirements are fulfilled. *Ibid.*

As reflected in the instant case, the parties to such litigation can use settlements to carve up the market between them to avoid the risks of competition. There is no indication, however, that Congress meant to pre-empt the application of settled

antitrust principles to such settlements. Indeed, prompted in substantial part by congressional concern over the competitive effects of agreements such as those at issue here, Congress amended the Hatch-Waxman Act as part of the 2003 Medicare Amendments, *supra*. Those amendments sought in part to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002). In the words of Rep. Waxman, "[t]he law has been turned on its head. * * * We were trying to encourage more generics and through different business arrangements, the reverse has happened." Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000, at A11 (quoting Rep. Waxman). Among the various corrective measures to address such abuses, the amendments require pioneer drug companies and generic applicants who enter into patent litigation settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118 (Pet. App. 360a-363a). In the event that such an agreement is found to violate the antitrust laws, the amendments provide that the generic party will forfeit any 180-day marketing exclusivity period it may have. 21 U.S.C. 355(j)(5)(D)(i)(V).

Experience has borne out the efficacy of this congressional scheme and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 19-20

(July 2002), <www.ftc.gov/os/2002/07/genericdrugstudy.pdf> ("*FTC Generic Drug Study*"). Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion.[2] These savings result from the pricing policies of generic sellers, which generally price at a substantial discount from branded drugs. As a result of such price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, branded drugs lose an average of 44 percent of their sales within the first full year after launch of a lower-priced generic product.[3]

2. Respondent Schering-Plough Corp. ("Schering") markets "K-Dur 20," a potassium supplement generally taken in conjunction with drugs for high blood pressure or congestive heart disease. See Pet. App. 2a-4a, 48a-52a. At the time of the subject agreements, K-Dur 20 was the most frequently prescribed potassium supplement, with annual sales reaching $170 million by 1997. The active ingredient in K-Dur 20, potassium chloride, is in common use and is unpatentable. Schering owns a formulation patent ("the '743 patent") that relates to the material that coats the potassium chloride crystals, providing an extended-release mechanism. The '743 patent expires in 2006. Thus, a generic manufacturer can use the active ingredient in K-Dur 20 without infringing Schering's patent, so long as it uses a coating material not covered by the '743 patent.

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[2] *Generic Pharmaceuticals Marketplace Access and Consumer Issues. Hearing Before the Senate Commerce Comm.*, 107th Cong. (April 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xiii (July 1998) ("*CBO Study*").

In 1995, two generic drug makers, ESI Lederle Inc. ("ESI") and respondent Upsher-Smith Laboratories, Inc. ("Upsher"), filed ANDAs for approval of generic versions of K-Dur 20, both with Paragraph IV certifications that the products they intended to market in direct competition with K-Dur 20 were non-infringing generic substitutes. Schering brought separate patent actions against ESI and Upsher, each within the respective 45-day period so as to trigger the 30-month automatic stay of FDA approval.

In late 1996, Schering and ESI began settlement negotiations. In March 1997, ESI proposed that Schering make a payment to ESI, in return for which ESI would delay its market entry. Pet. App. 251a-252a. The parties eventually reached such a settlement. *Id.* at 52a. A portion of the settlement covered a side deal for various product licenses, but it is undisputed that, separately, Schering agreed to pay ESI $15 million not to market any generic version of Schering's K-Dur 20 before January 2004. *Id.* at 142a n.101. Of that amount, $10 million had no proffered rationale other than warding off competition by ESI; ESI would receive it only if FDA approved ESI's application to sell its generic drug. *Ibid.* ESI ultimately obtained FDA approval, and Schering made the additional $10 million payment *Ibid.*

Two months after it began its settlement negotiations with ESI, Schering entered into settlement negotiations with Upsher. *Id.* at 97a. From the very first negotiating meeting, Upsher made a demand of $60-70 million from Schering to stay off the market. *Ibid.* On the eve of trial, Schering and Upsher entered into an agreement that settled their patent litigation. *Id.* at 50a. Schering agreed to make the unconditional, up-front $60 million payment Upsher had demanded, and Upsher agreed to forego marketing its generic product until September 2001. *Ibid.* Upsher also agreed to grant Schering a license to market six Upsher products in prescribed territories, with conventional royalties tied to the actual sales of those products. *Ibid.* The

$60 million unconditional payments were justified to Schering's board of directors as a "prerequisite of any deal" and as dictated by Upsher's desire for a guaranteed income stream to compensate it for lost revenue it otherwise would have earned from the generic potassium product. *Id.* at 97a n.78.

As a result of these agreements, Upsher and ESI remained off the market until 2001 and 2004, respectively, contrary to the parties' own prior expectations.[4] Market changes that occurred upon entry reflect the impact of the delayed entry. Upsher entered the market at a price approximately 50 percent of the price of K-Dur 20. Total branded Schering prescriptions fell from roughly 1,150,000 to approximately 390,000 within twelve months, and the lost 760,000 prescriptions were almost completely offset by sales of approximately 700,000 prescriptions of generic K-Dur. Pet. App. 72a-73a. Consumers thus saved many tens of millions of dollars in lower drug prices the first year after generic entry.

3. The Commission issued its administrative complaint in March 2001, charging that Schering's agreements with Upsher and ESI violated section 5 of the FTC Act, 15 U.S.C. 45. ESI entered into a consent agreement in April 2002, but respondents proceeded to trial; Schering sought to defend both agreements. An administrative law judge ("ALJ") dismissed the complaint in June 2002. Pet. App. 160a. The Commission reversed in December 2003, concluding on *de novo* review that the ALJ erred in several key factual findings and in his legal analysis.

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[4] Pre-settlement Schering documents showed that Schering had expected that generic entry would substantially erode its K-Dur 20 sales in 1998 and 1999. Pet. App. 69a. Upsher had similarly projected generic entry and lower prices starting in 1997, *id.* at 70a, and had informed the patent court in March 1997, after receiving tentative FDA approval, that the statutory stay on final approval was the only impediment to its immediate entry. *Id.* at 86a.

The Commission first determined that per se condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose. Pet. App. 60a-62a. Nevertheless, it concluded that the issue of market power could be addressed by direct proof of the effects of the introduction of generic K-Dur 20. *Id.* at 65a-67a (citing *IFD*, 476 U.S. at 460-461). The Commission found that there was abundant evidence that generic entry here was a "uniquely significant market event" that lowered prices and took substantial sales away from Schering, and therefore that delaying such entry had actual anticompetitive effects. *Id.* at 68a-75a.

The Commission then considered the exclusionary impact of the agreements in relation to that of the patent itself. It began with the observation that the strength of a patent does not depend simply on its expiration date, but on the probability that litigation will or will not prove the patent to be valid or, in this case, infringed. *Id.* at 81a-82a. Therefore, a hypothetical settlement in which the parties compromised on a time of entry without cash payments would reflect the strength of the patent as viewed by the parties. *Id.* at 75a-76a. The Commission further recognized, however, that Schering would not have made the large cash payments in this case without some *quid pro quo* and, in the absence of other consideration, it is logical to conclude that Schering was buying protection from the competition that could have resulted from the litigation. *Id.* at 76a-77a. The Commission found further support for this conclusion in the language of the settlement agreement and in the bargaining history – which, as noted above, began with Upsher's demand for a large cash payment. *Id.* at 77a. The Commission also considered whether a direct examination of the patent issues would be a better way to take account of the patent dispute in antitrust analysis, but concluded that such an inquiry was neither necessary nor appropriate here. *Id.* at 80a-

87a.[5] As the final step in its analysis, the Commission acknowledged that certain procompetitive effects of the agreements were "theoretically possible," *id.* at 61a, but found no evidence that those theories applied. *Id.* at 87a-92a.

With respect to the Upsher agreement, the Commission addressed in detail and rejected respondents' contention that the $60 million payment was entirely for side licenses conveyed under the agreement and not for Upsher's promise to delay its entry. Pet. App. 92a-141a. It found that the evidence demonstrated that the amount and unconditional nature of Schering's payment were based on Upsher's demand that it be compensated for its anticipated lost revenues during its absence from the market. *Id.* at 94a-107a. The Commission also rejected Schering's argument that one of the Upsher licences itself warranted the $60 million payment, finding that Schering's purported assessment of the Upsher product was belied by its own contemporaneous assessment of a similar product offered by a company that did not threaten it with generic competition.[6]

Schering's agreement with ESI evidenced on its face a promise to defer entry in exchange for cash payments. *Id.* at 142a. On those undisputed facts, and following the same

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[5] Although FTC staff argued that a post hoc adjudication of the underlying patent cases was unwarranted, it nonetheless also introduced evidence in support of the proposition that Schering faced a substantial risk that Upsher and ESI would be found not to infringe. Contrary to the court's assertion, however, the ALJ did not "evaluate[] the strength of the patent" (Pet. App. 15a), concluding that "the likely outcome of the patent disputes cannot be reliably predicted." *Id.* at 312a. He relied instead on an erroneous presumption of infringement. See *Id.* at 81a n.60.

[6] The Commission found Schering's product review perfunctory and not consistent with what Schering required in the past to evaluate a similar commercial opportunity. Pet. App. 108a-130a. Moreover, a more thorough and contemporaneous Schering analysis of a comparable product demonstrated that Schering in fact thought that those products did not justify a substantial, non-contingent payment. *Id.* at 111a-117a.

analytical approach it applied to the Upsher agreement, the Commission concluded that this agreement was an unreasonable restraint of trade. *Id.* at 142a-145a.

4. On Schering's and Upsher's petitions for review, the court of appeals set aside the Commission's decision. *Id.* at 2a. The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents, and that the analysis must instead focus on the "exclusionary potential" of the patent, and whether the agreements had exceeded that potential. *Id.* at 16a-17a (citing *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co.* v. *Abbott Labs.*, No. 03-1178 (Oct. 12, 2004)). In assessing the exclusionary potential of the '743 patent, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the * * * patent was invalid or that their products * * * did not infringe Schering's patent," *id.* at 18a, and noted that there was no allegation that the patent claim was a "sham." *Id.* at 20a.

In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment. In the case of the ESI agreement, for example, the court held that the $10 million payment that was directly linked to regulatory approval of the generic drug and for which no other consideration was attributed was lawful because it was "within the patent's exclusionary power." *Id.* at 28a. The court also cited, as to both agreements, the presumed public policy benefits of the settlement of litigation. *Id.* at 28a-29a. The court concluded that the existence or size of such a payment cannot be used to show that the patent holder has obtained a greater degree of market exclusion than its patent justified. *Id.* at 35a.

Despite these legal holdings, the court of appeals nevertheless reviewed and rejected the Commission's extensive factual findings in support of its conclusion that Schering had paid Upsher for delayed entry. *Id.* at 21a-26a. The court was particularly critical of the Commission's decision not to accept the "credibility" determinations of the ALJ (*id.* at 25a-26a), but declined to address the Commission's stated reasons for reaching its conclusions. *Cf. id.* at 94a-96a. The court of appeals criticized the Commission for taking the economic incentives of the parties into account in assessing the plausibility of their claims that the side deal itself warranted the $60 million payment. *Id.* at 23a-25a. The court referred to "overwhelming" evidence in support of the ALJ's findings (*id.* at 25a, 26a), but did not identify any such evidence.

REASONS FOR GRANTING THE PETITION

This case merits review by this Court to correct fundamental legal errors by the court of appeals that not only depart from settled antitrust and administrative law principles, but also dramatically alter Congress's intended balance between the patent and antitrust laws as applied to generic drugs. Contrary to this Court's teachings, the court of appeals' ruling essentially imposes a rule that a patentee is presumptively entitled to buy protection from all competition for the full patent term, even if such payments effectively augment the patent's actual exclusionary power. To fashion this rule, the court candidly stated that, to resolve this antitrust case, it would apply "neither the rule of reason nor the per se analysis" but would reach a result that "reflects policy." Whatever the source of that policy, it cannot be found in the Patent Act, which recognizes that infringement is not to be presumed but proven by the patentee; the Hatch-Waxman Act, which seeks to stimulate generic challenges to branded drugs; or the antitrust laws, which

prevent monopolists from buying off would-be rivals by the simple device of sharing monopoly profits with them.

Review of this error is urgently needed because the ruling below could seriously impede the Commission's law enforcement efforts on behalf of consumers nationwide. In light of the large number of leading drugs that are the subject of patent challenges, the economic stakes for the American consumer in this issue are staggering.

The court of appeals' reversal of the Commission's factual findings regarding the Upsher agreement also warrants review, because it departs so drastically from the established standard of appellate review. This issue does not, however, affect the court of appeals' analysis of the ESI agreement, which independently warrants the grant of *certiorari* on Question 1.

I. THE COURT OF APPEALS ERRED IN RULING THAT AGREEMENTS BETWEEN COMPETITORS ARE LAWFUL IF WITHIN THE "POTENTIAL" REACH OF A PATENT CLAIM.

1. The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is "clearly anticompetitive," and hence unlawful unless excused by the lawful exercise of patent rights. Pet. App. 13a. This Court has repeatedly dealt with analogous situations. See, *e.g.*, *United States* v. *Masonite Corp.*, 316 U.S. 265, 274 (1942); *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 455 (1940). In such cases, the overarching principle is clearly established: that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement." *Masonite*, 316 U.S. at 277; *Ethyl*, 309 U.S. at 456; *United States* v. *Line Material Co.*, 333 U.S. 287, 308 (1948), even if the agreement takes the form of a litigation settlement. See *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (White, J., concurring) (competitors' collusive

termination of a patent interference proceeding to help broaden the patent's scope runs afoul of the Sherman Act). Although the court of appeals acknowledged this principle, Pet. App. 18a, it failed to appreciate that parties settling litigation deal in uncertainties, and that the elimination of the prospect of competition, even if uncertain, harms consumers. The standard the court set down gives patentees free rein to "buy off" potential competitors, even in the context of generic drugs, where Congress has specifically sought to promote patent challenges to facilitate non-infringing generic entry.

The sweeping nature of the court of appeals' rule derives from its approach to assessing the "exclusionary potential of the patent." Pet App. 17a. The court based its reasoning upon the statutory presumption of patent validity, 35 U.S.C. 282, and upon a demonstrably *incorrect* extension of that presumption to the patent infringement issues most relevant here,[7] and ruled that the "exclusionary power" of the patent at issue here encompassed a right to exclude both Upsher and ESI from the market "until they proved either that the '743 patent was invalid or that their products * * * did not infringe Schering's patent." Pet. App. 18a. Although the court appeared to acknowledge that the presumptions it relied upon could be overcome by "evidence to the contrary," *id.* at 20a, the only circumstance in which it indicated the parties would exceed the exclusionary potential of the patent was that of "sham" infringement claims. *Ibid.* Furthermore, in light of the same court's earlier ruling that an exclusionary settlement could not be condemned "merely because the patent is subsequently declared invalid," in the absence of a showing such as that the

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[7] The Federal Circuit has consistently held that the patent holder has the burden of proving infringement by a preponderance of the evidence. See, *e.g.*, *Kegel Co., Inc.* v. *AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997); *Wolverine World Wide, Inc.* v. *Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994).

patentee "knew" that the patent was invalid or not infringed, *Valley Drug*, 344 F.3d at 1306, 1308-1309, it appears that the court below would recognize only limited exceptions to its rule that settlements within the outer, nominal bounds of patent claims are presumed lawful.

The court of appeals' formalistic approach to the issue of the "exclusionary potential" of the patent ignores the most salient factor that gives rise to patent litigation and settlements, the existence of *uncertainty* regarding whether a patent is valid, or (as was the focus here) infringed by particular products. Upsher and ESI stood as potential competitors to Schering's K-Dur; they could offer competing products unless Schering demonstrated that their products infringed. It is a fundamental principle of antitrust law, however, that it is unlawful to enter into an agreement in which potential competitors (even those whose successful entry is uncertain) agree to stay out of a market. See *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam).[8] "[T]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States* v. *Griffith*, 334 U.S. 100, 107 (1948) (citation omitted); see also *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash

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[8] In that case, the court of appeals had accepted the view that the agreement of one party (BRG) not to enter into the bar review business outside of the state of Georgia could not be condemned as a market allocation agreement, because "BRG had never done business outside the state of Georgia, [and] nothing in the record suggested that it ever intended to do so * * *." 874 F.2d 1417, 1424 (11th Cir. 1989). This Court rejected that reasoning, holding that "[s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business * * *." 498 U.S. at 49-50. As one leading commentator has put it, citing *Palmer*, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, *Antitrust Law*, ¶ 2030b, at 175 (1999).

nascent, albeit unproven, competitors at will"). Had Schering paid substantial sums of money to a potential generic to delay entry, where the only impediment to entry was uncertainty about the generic's ability to obtain FDA approval, there would be no question that such an agreement was anticompetitive. See *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 806-809 (D.C. Cir. 2001) (uncertainty of FDA approval does not preclude antitrust claim). There is no reason why uncertainty regarding patent litigation should be treated differently.

Although all property rights are subject to legal uncertainties, the "probabilistic" nature of the property interest created by the patent laws[9] makes it especially important to take such uncertainty into account. Unlike forms of property that are defined in terms of title to tangible items with clearly defined boundaries, the exercise of rights conferred even by a valid patent requires that the boundaries of the patent's coverage be delimited in relation to an accused infringing product. "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added). When it asserts its patent and threatens a lawsuit, the patentee can hope that the strength of its patent will either convince the accused infringer to accede or convince a court to issue an injunction, but neither path guarantees success. As both economists and legal scholars have remarked, "a patent is not a right to exclude, but rather a right to *try* to exclude."[10]

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[9] See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005); Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391, 395 (2003).

[10] Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1761 (2003) (emphasis added); see Shapiro, *supra* note 9, at 395.

Available empirical data reinforce the importance of taking such uncertainties into account in any practical assessment of the "exclusionary potential" of a patent claim. A study examining nearly all written, final validity decisions by the district courts and the Federal Circuit from 1989 through 1996 found that 46 percent of patents challenged in litigation were invalidated. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998). As discussed above, the percentage of vulnerable patent claims appears to be even greater in the Hatch-Waxman context, in which branded companies have often aggressively made multiple patent claims for drugs facing generic challenge. See *FTC Generic Drug Study* at 19-20.

2. Accordingly, a realistic assessment of whether a patentee settling a disputed claim has "extend[ed] his statutory grant by contract or agreement," *Masonite*, 316 U.S. at 277, must consider whether the patentee has eliminated the possibility of competition by paying off rivals to give up their claims. Suppose, for example, that there is a 50-50 chance that a patent-holder will prevail in litigation to keep a particular product off the market, and thus a 50 percent chance of entry yielding immediate benefits to consumers (assuming the patent conveys market power).[11] If the patent holder and challenger enter into a settlement in which the challenger gives up the right to enter,

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[11] The Commission found, based on the special circumstances surrounding the entry of generic drugs and on the specific experience upon the introduction of a generic version of Schering's K-Dur, that delay in that introduction had substantial adverse effects on consumers, and that, under this Court's teachings in *California Dental Ass'n* v. *FTC*, 526 U.S. 756 (1999), and in *IFD*, *supra*, the presence of such effects obviates any more extensive market inquiry. Pet. App. 64a-75a. Although the court of appeals made critical reference to this portion of the Commission's opinion in passing, Pet. App. 15a-16a, it did not base its ruling on this point. Its own discussion of "competitive effects," Pet. App. 28a-35a, focused entirely on the ostensible competitive justifications for the restraints.

for the remaining term of the patent, in return for a cash payment from the patentee, consumers would lose the 50 percent chance they had of enjoying the benefits of competition. As the Commission recognized, settlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent. Pet. App. 75a-76a.

If, however, the patent holder makes a substantial payment to the challenger as part of the deal, "absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 76a-77a (footnote omitted). The court of appeals rejected this reasoning as a matter of law, dismissing out of hand the notion that "the size of the payment [by the patentee], or the mere presence of a payment" should have any bearing on the antitrust analysis of an agreement of this sort. Pet. App. 34a. The court of appeals' reasoning ignores the fact that a firm "certain that a patent was valid * * * would have no incentive whatsoever to pay another firm to stay out of the market." Herbert Hovenkamp, *Antitrust Law*, ¶ 2046, at 339 (2004 Supp).

Moreover, contrary to the court of appeals' assumption, the Commission's analytical approach did not turn on "the untenable supposition that without a payment there would have been different settlements * * *, resulting in earlier entry dates." Pet. App. 17a n.15. The Commission's analysis never assumed that different settlements between the parties would necessarily have replaced those under investigation. Rather, the Commission used a *hypothetical* no-payment compromise as a benchmark to assess "'the difference between the amount of competition [resulting from the actual settlements] * * * versus the amount of competition that was likely to occur had it not been

for the payment to delay * * *.'" Pet. App. 76a (quoting expert witness). Where a patent holder makes a payment to a challenger in order to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[12]

The court of appeals' treatment of the settlement between Schering and ESI clearly illustrates its error. As to that agreement, the Commission assumed that Schering had paid $15 million for a purported side deal and $5 million to defray litigation costs, and did not rely on those payments. See Pet. App. 144a. The Commission pointed out, however, that there was no proffered justification for the $10 million payment -- which was expressly contingent on ESI's obtaining the FDA approval that would allow it to enter the market -- other than ESI's "adaman[cy]" that such a payment was necessary "to get ESI's agreement on settlement terms that delayed generic entry until 2004." *Ibid.* The court of appeals refused to consider the relationship between the payment and the increased likely level of exclusion, instead opining that the agreement was necessarily lawful because the patent issue remained subject to "fierce" dispute, and the settlement was "within the patent's exclusionary power," as incorrectly defined by the court. Pet. App. 28a.

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[12] For example, to return to the hypothetical patent claim with a 50 percent chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

3. The legal environment in which the parties entered into these restrictive agreements makes the court of appeals' error all the plainer. To establish the governing national policy in this area, Congress has twice addressed the matter of patent rights regarding branded and generic drugs, first in the Hatch-Waxman Act and then in the 2003 Medicare Amendments. In those enactments, it went to great lengths to encourage challenges to vulnerable patent claims, for the purpose of promoting early non-infringing generic entry. For example, Congress encouraged the early commencement of patent litigation – and linked it to the regulatory process – by defining the filing of an ANDA with a Paragraph IV certification as a "new (and somewhat artificial) act of infringement" that allows the patentee to bring suit without waiting for the generic company to enter the market. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 35 U.S.C. 271(e)(2).[13] The statute also affords the first ANDA applicant a period of exclusivity, as a further incentive to encouraging patent challenges. 21 U.S.C. 355(j)(5)(B)(iv). These provisions reflect Congress's recognition that many infringement claims are indeed vulnerable, and that consumers will benefit through successful challenges. Moreover, the pertinent provisions of the 2003 Medicare Amendments, which were prompted in part by the very antitrust concerns raised in this case,[14] further these congressional policies by requiring that

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[13] Furthermore, Congress gave patent holders a strong incentive to bring such patent litigation promptly, by affording them an automatic 30-month stay of FDA approval for the ANDA if (but only if) they commence suit within 45 days. 21 U.S.C. 355(j)(5)(B)(iii).

[14] See, *e.g.*, S. Rep. No. 167, *supra*, at 4 ("the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives").

parties entering into the settlement of patent litigation involving pharmaceuticals file such settlements with the Commission and the Department of Justice for review, and by imposing the added sanction of loss of any marketing exclusivity period for a generic manufacturer found to have violated the antitrust laws. See Pub. L. No. 108-173, § 1112 (Pet. App. 360a-361a); 21 U.S.C. 355(j)(5)(D)(i)(V).

The court of appeals' approach to antitrust analysis of patent settlements in the Hatch-Waxman context will vitiate these congressional enactments. Pharmaceutical companies have strong economic incentives to enter into the sort of anticompetitive agreements the court of appeals condoned in this case. In nearly any case in which a generic contemplates market entry, the profit that the generic anticipates will be well under the profit that the branded manufacturer would make from the same volume of sales.[15] Accordingly, absent antitrust constraints, it will almost always be profitable for the branded manufacturer to buy off generics by offering them as much or more than they would make by entering, thus securing continued exclusivity and the continued ability to charge monopoly prices.[16] Furthermore, by setting such a high bar for a showing that a patentee has exceeded the exclusionary power of the patent, the court of appeals' ruling would make Congress's recent directive that drug patent settlements be reported to the antitrust enforcement agencies for review a pointless gesture.

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[15] See *CBO Study*, at xiii (generic versions cost on average 25 percent less than original brand-name drugs at retail prices); *id.* at 28 (wholesale price of generic drugs about half that of brand-name drugs in the first year after generic entry).

[16] In the majority of past instances of such agreements, competition was barred for the *entire* nominal duration of the patents. See *FTC Generic Drug Study* at 31.

The inconsistency between the court of appeals' ruling and congressional policy is especially clear in the court's treatment of the ostensible competitive benefits of patent settlements. See Pet. App. 29a-35a. The court invoked the general public policy preference for the settlement of litigation, citing the prospect of cost savings and the achievement of "certainty" regarding patent rights. *E.g., id.* at 29a, 30a, 33a. The court noted that the Hatch-Waxman Act altered the bargaining positions of the respective parties, and may make a conventional settlement more difficult to reach in some cases. *Id.* at 31a. In fact, the court's dire warnings that the Commission's approach would impede settlements (*id.* at 34a) are entirely unwarranted. As the Commission recently reported, pursuant to Congress's directive in the 2003 Medicare Amendments, legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise.[17]

More important, the court of appeals drew entirely the wrong lesson from Congress's modification of the respective rights of patent holders and challengers in the pharmaceutical context. Congress made those changes for the very purpose of benefitting consumers by fostering successful challenges and permitting early entry of non-infringing generics. The court of appeals' ruling nullifies this congressional choice, for no discernible public gain, by excusing otherwise unlawful collusive actions in order to allow the patent holder to "realize[] the full potential of its infringement suit." *Ibid.* The court of appeals' ruling, avowedly "reflect[ing] policy," *id.* at 35a, flatly contradicts the policies of Congress.

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[17] See Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004 - A Report by The Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/-2005/01/050107medicareactrpt.pdf>.

II. REVIEW IS NEEDED TO ENSURE UNIFORMITY ON AN ISSUE OF EXCEPTIONAL NATIONAL IMPORTANCE.

Review of the foregoing issue is needed not only because of disarray among the lower courts on this issue, but because of the dramatic impact the present ruling could have on U.S. consumers. Another court of appeals appears to have taken a strikingly different approach, ruling that it may be per se unlawful for a patent holder to "bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor * * * to stay out of the market." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (footnote omitted), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004). Although a number of circumstances made that interlocutory case a poor vehicle for plenary consideration of the issue,[18] the present case comes to the Court on a full record. Moreover, the ruling below has sharpened the tension between the Sixth and Eleventh Circuits. See *supra*, at 14-16.

Practical considerations magnify the impact of the ruling below on law enforcement in this area. The Commission has brought a number of administrative cases challenging pharmaceutical patent settlements, all of which except the present one

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[18] As the United States pointed out in an amicus brief in which the Commission joined, the *Cardizem* ruling was not only interlocutory but involved an unusual fact pattern involving an "interim" settlement that precluded entry during patent litigation but did not bring that litigation to an end. See Brief for the United States As Amicus Curiae, at 7, 15-18, *Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (*certiorari denied* Oct. 12 2004). Moreover, the *Cardizem* court's reference to the possibility that the agreement there extended to non-infringing products, 332 F.3d at 908 n.13, cast doubt on the reach of its per se rule.

led to the entry of consent orders.[19] Yet, because the Commission's administrative decisions are reviewable in any circuit in which the respondent resides or does business, 15 U.S.C. 45(c), any substantial pharmaceutical company involved in a future case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit.

The economic implications of the court of appeals' ruling, which invites collusive arrangements between branded drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[20] In recent years, facilitated by the incentive structure of the Hatch-Waxman Act, numerous generic manufacturers have successfully challenged listed patents and entered prior to the expiration dates of those patents. See *FTC Generic Drug Study*, at 19-20 (generics prevailed in cases involving 73 percent of challenged drug products). Successful challenges have included a number of "blockbuster" drugs with annual sales in the billions of

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[19] *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001); *Geneva Pharms., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000); *Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000).

[20] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. See The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4 percent annually from 1993-2003, almost triple the average inflation rate of 2.5 percent during that same period. *Ibid.*; see also Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2003*, at 1 (January 11, 2005) (prescription drug spending rose 14.9 percent in 2002 and 10.7 percent in 2003). They are projected to increase at an even higher average rate over the next decade (10.7 percent annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id.* at 1.

dollars.[21] The entry of generic drugs into such markets invariably results in dramatically lower prices for consumers and health care payors.[22] There is every indication, moreover, that this process has the potential to continue to provide consumer benefits. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, currently are the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[23] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the court of appeals' ruling, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and

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[21] See, *e.g.*, *SmithKline Beecham Corp.* v. *Apotex Corp.*, 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming the antidepressant Paxil held invalid); *Astra Aktiebolag* v. *Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom. In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. Dec. 11, 2003) (generic manufacturer did not infringe patents claiming anti-ulcer drug Prilosec); *Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid).

[22] See *CBO Study*, at ix (consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone); Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004) (patients can save up to 52 percent in prescription drug costs by purchasing generic versions of brand-name drugs).

[23] See Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, *e.g.*, Pfizer Inc., *Form 10-Q* (Aug. 8, 2005); Wyeth, *Form 10-Q* (Aug. 5, 2005); Purdue Pharma, L.P., *Press Release* (June 8, 2005).

deprive consumers of the benefit of low-cost, non-infringing generic drugs.

III. THE COURT OF APPEALS GROSSLY MISAPPLIED THE SUBSTANTIAL EVIDENCE STANDARD.[24]

This case is also one of the rare instances in which the Court should intervene to correct a gross misapplication of the "substantial evidence" standard of review. Although the task of determining whether substantial evidence supports agency findings is ordinarily left to the courts of appeals, see *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1951), this Court has not hesitated to intervene when a court's misapprehension or, as in this case, gross misapplication of the standard threatened the effective application of the antitrust laws. See, *e.g.*, *IFD*, *supra*.

Section 5 of the Federal Trade Commission Act provides that "[t]he findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. 45(c). This language has long been understood to apply the "substantial evidence" test of the Administrative Procedure Act, 5 U.S.C. 706(2)(E). See *IFD*, 476 U.S. at 454. The test is whether the Commission's findings are supported by "such relevant evidence as a reasonable mind might accept as adequate," *ibid.* (quoting *Universal Camera*, 340 U.S. at 477), not whether the reviewing court, "'mak[ing] its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences,'" would reach the same conclusion.

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[24] Question 2 of the Petition, addressed in this part, applies only to the agreement between Schering and Upsher. No such factual dispute exists with respect to the agreement between Schering and ESI. Accordingly, regardless of whether review is granted on this question, review of Question 1 is nevertheless appropriate in light of the gravity of the court of appeals' error and the great importance of the issue.

IFD, 476 U.S. at 454 (quoting *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 73 (1934)).

As explained above, the pivotal factual issue regarding the Upsher agreement was whether the $60 million payment was, in substantial part, a *quid pro quo* for Upsher's agreement not to compete until 2001, rather than an up-front, unconditional "royalty" for the product licenses that Schering obtained. The Commission examined this issue in great detail, Pet. App. 92a-141a, focusing on a license for a niacin product that the parties acknowledged was the primary item of supposed value. See *id.* at 108a n.83. The court of appeals' discussion reflects a consistent refusal to accord any weight to the reasoned conclusions of the agency entrusted with adjudicating these matters. See 15 U.S.C. 45(b). The court begins, for example, by impugning expert testimony on which the Commission did *not* rely, on the premise that the Commission's conclusions were "curiously" similar. Pet. App. 22a-24a. Then, the court dismisses the evidence upon which the Commission did rely, but entirely ignores the Commission's own explication of the record. For example, the court chastises the Commission's "non-expert opinion that Schering should have done more due diligence" in its evaluation of the niacin product. *Id.* at 24a. But the Commission's conclusions were based on no such second-guessing, but rather on the *inconsistency* between Schering's actions here and its own actions in assessing a similar commercial opportunity presented by a company that did not threaten it with generic competition. *Id.* at 108a-111a, 122a-130a.[25] Moreover, the court of appeals simply ignored the

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[25] The other product was clinically similar, and evidence showed that it presented a less risky opportunity, having already received clinical approval by the FDA. See Pet. App. 111a-116a. Schering declined to offer any up-front payment for that product, after detailed investigation. *Id.* at 116a-117a. By contrast, Schering purported to assign a high value to Upsher's unapproved product, following a more cursory investigation, and despite the

most damning, contemporaneous, and documentary evidence on which the Commission relied.[26] And, although the court of appeals made the conclusory holding that the evidence supporting its view was "overwhelming," *id.* at 25a, 26a, it cited to no such evidence.

Two aspects of the court of appeals' analysis are particularly troubling, and plainly at odds with this Court's teachings regarding appellate review of agency findings. First, the court below criticized the Commission's recognition of the economic motivations facing Schering and Upsher in drawing inferences about the $60 million payment. See *id.* at 23a-24a. But agencies are allowed to draw on their familiarity with the subject matter entrusted to them by Congress. See generally *Dickinson* v. *Zurko*, 527 U.S. 150, 160-161 (1999) (discussing reasons for deference to agency factfinding). Business practices and the economic incentives facing businesses are at the heart of the FTC's institutional expertise, and, as this Court has recognized, the Commission is entitled to rely on "common sense and economic theory" in its administrative adjudications. *IFD*, 476 U.S. at 456. Second, the court of appeals erred in deferring to the "credibility" determinations of the ALJ, rather than to the Commission's findings. Pet. App. 25a. This Court has instructed that the substantial evidence "standard is not modified in any way when the [agency] and its examiner disagree," *Universal Camera*, 340 U.S. at 496. The present circumstances underscore the wisdom of that principle. The finding at issue was not a simple fact such as who had said

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fact that the contract contained no commitment by Upsher to carry through in obtaining approval. *Id.* at 122a-130a.

[26] The Commission had relied, for example, on the terms of the agreements themselves, Pet. App. 93a-94a, and on Schering's presentation to its board of directors, which explained that the payments represented lost revenue for the period Upsher stayed off the market, *id.* at 97a n.78.

what at a particular meeting, but the broader question whether Schering and Upsher had entered into the side licensing agreement as an end in itself or in order to facilitate (and perhaps mask) large payments intended to keep Upsher out of the market. While the testimony of Schering executives is relevant to the inquiry, as the Commission acknowledged, Pet App. 96a n.77, its plausibility must be weighed against the entire record. The Commission is the body entrusted by Congress with making such determinations. On *de novo* review, the Commission unanimously disagreed with the ALJ's factual determination, and its final ruling was entitled to deference. The court of appeals' analysis shows that it failed to afford such deference.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION AND
UPSHER-SMITH LABORATORIES, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Whether the Court of Appeals' application of the "substantial evidence" standard warrants this Court's rare intervention, where the Court of Appeals correctly stated the standard to be applied, said it was applying that standard, and detailed its reasons for finding that, on a review of the whole record, the Commission's findings were not supported by substantial evidence, and where the factual question at issue is one in which the agency has no expertise.

2. Whether a settlement of patent litigation between a pharmaceutical patent-holder and an alleged generic infringer that enabled generic entry years before patent expiration is an unreasonable restraint of trade simply because the settlement included a payment to the alleged infringer, regardless of the merits of the patent infringement claims and without any proof that some "better" settlement would have been achieved without a payment.

CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 29.6 of the Rules of the Supreme Court of the United States:

Respondent Schering-Plough Corporation hereby advises the Court that:

(1) Schering-Plough Corporation has no parent corporation; and

(2) No publicly held company owns 10% or more of the stock of Schering-Plough Corporation.

Respondent Upsher-Smith Laboratories, Inc. hereby advises the Court that:

(1) Upsher-Smith Laboratories, Inc. has no parent corporation; and

(2) No publicly held company owns 10% or more of the stock of Upsher-Smith Laboratories, Inc.

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STATEMENT OF THE CASE

1. Introduction

This petition for a writ of certiorari arises out of the Federal Trade Commission's program of challenging pharmaceutical patent-infringement litigation settlements entered into in the 1990s where 1) the settlement included a payment from the patent holder to the alleged infringer and 2) the alleged infringer agreed to stay off the market for some portion of the remaining life of the patent.

In this case, the Federal Trade Commission ("Commission") challenged the settlement of two different patent-infringement lawsuits brought by Schering-Plough Corp. ("Schering"): one against Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), and one against ESI Lederle Inc. ("ESI"). In each settlement, the parties compromised on a market entry date, permitting the alleged infringer to enter the market long before patent expiration. Both the Commission's Administrative Law Judge ("ALJ") and the Court of Appeals found that the Commission's challenges lacked any merit. The Commission seeks a writ of certiorari to review the Court of Appeals' decision.

This case is an exceedingly unappealing candidate for review by this Court, for several reasons.

A. The Commission lost its challenge to the principal settlement involved in this matter—the Schering/Upsher-Smith settlement—because of the Commission's inability to prove as a factual matter that there was a net "payment." As part of that settlement, Schering paid Upsher-Smith $60 million for rights to Niacor-SR, a cholesterol treatment drug that Upsher-Smith was developing, and several other Upsher-

Smith products. Niacor-SR was in no way involved in the patent suit. The Commission conceded that if the $60 million payment was a *bona fide* fair-value payment for the rights to Niacor-SR and the other products, then its case failed. Both the Commission's ALJ, who presided over the ten-week trial, and the Court of Appeals ruled against the Commission on this threshold fair-value question. This was a pure fact issue, and it is not suitable for review by this Court.

Nor does the Commission's challenge to the settlement of the Schering/ESI suit even remotely warrant review by this Court. The Commission introduced very little evidence about the ESI settlement at trial, and acknowledged in its decision that, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a. The ESI settlement was the product of fifteen months of court-supervised mediation. The relatively small payment of $15 million was agreed to at the urging of the United States Magistrate Judge who functioned as the mediator. The expert testimony showed that Schering had an extremely strong patent case, and that the compromise entry date agreed to in the settlement fairly reflected the strength of that case. And, as the Court of Appeals observed, "[t]he FTC did not rebut this testimony, but rather ignored it." Pet. App. at 27a.

B. The Commission's claim that the Court of Appeals *misapplied* the standard of review of administrative agency fact finding does not raise a cert-worthy issue. The Court of Appeals fully, faithfully and correctly articulated the applicable standard of review in accordance with this Court's pronouncements in *Universal Camera v. NLRB*, 340 U.S. 474 (1951). This Court does not generally review claims that a "properly stated rule of law" was misapplied. *See* SUP. CT. R. 10.

C. The Commission's petition greatly overstates the extent to which the Court of Appeals' antitrust analysis differs from its own. The Court of Appeals, the Commission, and the Department of Justice *all agree* that the payment of money as part of a patent settlement in which the alleged infringer agrees to stay off the market for a period of time is *not* a *per se* violation of the antitrust laws. This is so because the patent may confer a *lawful* right to exclude the would-be competitor from the market. Consequently, all agree that the antitrust analysis must include a comparison of the exclusionary effect of the settlement agreement with the legitimate exclusionary power of the patent. *See* Pet. at 9. The problem for the Commission is that the Court of Appeals found that the Commission did not make this comparison correctly. This finding does not raise a cert-worthy issue either.

Notably, the Commission joined the Department of Justice in urging the Court to deny certiorari in a similar pharmaceutical patent-litigation case just last term in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharmaceuticals, Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004). *See Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL 1562075 (July 2004). In their opposition to certiorari in *Cardizem/Andrx*, the Commission and the Department of Justice urged that both the absence of a circuit split on the antitrust analysis and the recent amendments to the Hatch-Waxman Act in 2003 counseled against certiorari. This issue was not worthy of certiorari last term, and it remains unworthy of certiorari today.

D. The claim in the Commission's petition—a petition that is not joined by the Department of Justice—that the decision of the Court of Appeals will have a substantial

effect on consumers is suspect.[1] Patent settlements involving payments to the allegedly infringing generic company do not appear to be recurring. The Commission itself stated in a recent report that since 1999 "the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product."[2]

2. The Patent Infringement Settlements

Schering owns a duly-issued patent covering the sustained-release mechanism in a potassium chloride supplement called K-Dur. That patent is valid and in effect today. It expires on September 1, 2006. Pet. App. at 50a. Notably, the active ingredient in K-Dur, potassium chloride, is widely used and unpatentable. *Id.* at 2a. Indeed, even before marketing its generic version of K-Dur, Upsher-Smith and many other pharmaceutical companies produced and marketed potassium chloride supplements used to treat the same potassium deficiency as K-Dur. Pet. App. at 165a-175a.

The Upsher-Smith Settlement

In late 1995, Upsher-Smith sought FDA approval to market a generic version of K-Dur, and Schering sued Upsher-Smith for patent infringement. After a year and a half of litigation, the parties settled the patent infringement

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[1] *See* 15 U.S.C. § 56(a)(3)(A) (2005) (requiring the Commission to consult with the Solicitor General before petitioning for certiorari).

[2] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B].

suit in June 1997, just before trial. Pet. App. at 50a. Under the terms of the settlement, Upsher-Smith could market its generic product after September 1, 2001, but not before. Pet. App. at 194a. This compromise market entry date was five years before the date Schering's patent expires. *Because of this settlement*, Upsher-Smith's generic product has been on the market for over four years as of the date of this filing. If the parties had continued the litigation and Schering had prevailed, Upsher-Smith's product would have been excluded from the market until Schering's patent expires in September 2006. *See* Pet. App. at 20a.

As part of the settlement, Schering paid $60 million for the license rights to Niacor-SR, a sustained-release niacin product that Upsher-Smith was developing, and a bundle of other products. Pet. App. at 195a. Niacor-SR, a product in no way involved in the patent case, was the most valuable of these products.

The ESI Settlement

In late 1995, ESI sought FDA approval for a generic version of K-Dur, and Schering sued ESI for patent infringement. Pet. App. at 249a. In the fall of 1996, at the urging of the trial judge, the parties agreed to engage in court-supervised mediation. Pet. App. at 250a. United States Magistrate Judge Thomas Rueter was appointed as mediator, and he supervised numerous mediation sessions over the course of fifteen months. *Id.* Finally, in December 1997, the parties agreed on a compromise market entry date that would permit ESI to market its generic product after December 31, 2003 but not before. Pet. App. at 7a, 254a-255a. ESI still would not settle without a payment from Schering.

A settlement in principle finally was reached on January 23, 1998 in a late-night mediation session in Judge Rueter's chambers. Pet. App. at 256a-257a. Judge Rueter

prevailed upon Schering to pay ESI $5 million, which he characterized as "nothing more than legal fees." Pet. App. at 7a. Next, Judge Rueter and Schering discussed a concept under which Schering would pay ESI up to $10 million more, but only if ESI received FDA approval by a certain date. Pet. App. at 7a, 257a-258a. Schering agreed, believing that ESI would *not* get its drug approved,[3] and that Schering would never have to pay the additional $10 million. *Id.* Judge Rueter asked the parties to write up the settlement terms and sign them that night. Pet. App. at 258a. It is undisputed that Judge Rueter was present at the preparation and signing of that January 23, 1998 handwritten agreement, and was aware of all the terms, including the payments from Schering to ESI. Pet. App. at 7a.

3. The FTC Complaint and the Trial

In April 2001, the Commission filed an administrative complaint alleging that Schering's two patent-litigation settlements restrained trade in violation of the antitrust laws.

The Upsher-Smith Settlement: the Fair-Value Issue

The ALJ appointed by the Commission presided over a ten-week trial that included dozens of witnesses and thousands of documents admitted into evidence. The central fact issue at trial was whether the Upsher-Smith settlement contained a net "payment" from Schering to Upsher-Smith, or whether Schering's $60 million payment was a *bona fide* fair-value payment for Niacor-SR and the rights to the other Upsher-Smith products. The Commission had conceded that if Schering's $60 million payment was fair value for all those

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[3] Schering had recently learned that the FDA had twice rejected ESI's clinical studies, and ESI was just beginning to re-do them. Pet. App. at 253a-254a.

rights, the Upsher-Smith settlement was lawful. Pet. App. at 92a. ("Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher.").

The Schering employees who had evaluated Niacor-SR testified and were cross-examined fully at trial. They were unaware of the patent litigation when they conducted their evaluation. Pet. App. at 22a, 191a, 319a. They were well qualified for the task. Pet. App. at 217a-219a, 319a. They had access to the results of Upsher-Smith's pivotal clinical trials for Niacor-SR. Pet. App. at 221a. And they testified that, in their best business judgment, the rights to Niacor-SR were worth more than $60 million. *See* Pet. App. at 227a-228a. Their testimony was supported by contemporaneous documents showing that they had projected Niacor-SR sales to exceed $100 million per year starting in its third year on the market, bringing Schering a profit stream with a net present value of $225-$265 million. Pet. App. at 224a-225a, 227a, 319a-320a.

Their testimony was also powerfully corroborated by testimony that another team within Schering had earlier evaluated another similar sustained-release niacin product, and had developed written sales projections for that product that were closely comparable to the Niacor-SR sales projections. Pet. App. at 6a, 22a, 111a, 115a, 209a, 213a, 318a. In addition, Schering called an independent pharmaceutical licensing expert who testified that Schering could have paid as much as $100 million for Niacor-SR (i.e., $40 million more than Schering paid for Niacor-SR *and* the bundle of other product licenses) and still made a substantial return based on the expert's "conservative" estimate of Niacor-SR's projected economic value. Pet. App. at 227a-228a.

Schering also introduced the testimony of independent members of its Board of Directors. Those directors testified that the Board had been asked to evaluate the Niacor-SR license (along with the bundle of other product licenses) *as a stand-alone deal*, and to approve the licenses only if they were sufficiently valuable to Schering, separate and apart from the settlement agreement. Pet. App. at 197a-198a. The Board concluded that they were, based on Schering's internal evaluation described above, and approved the payment for the licenses. Pet. App. at 199a. The Board was not asked to approve the settlement.[4]

By contrast, the Commission, in its case in chief, presented no fact witnesses on the valuation issue. Instead, the Commission's trial counsel relied solely on the testimony of one expert witness with experience in valuing rights to pharmaceutical products. Pet. App. at 320a. That expert's testimony was so badly discredited on cross-examination, however, that neither the ALJ *nor the Commission* relied on it. *See* Pet. App. at 130a, 320a-321a. The Commission again affirmatively disclaims any reliance on that expert in its petition. Pet. at 27.

The Upsher-Smith Settlement: the Antitrust Issue

The Commission presented an economic expert who testified that, as a matter of theory, a settlement with a payment necessarily would deliver less competition than

[4] The petition asserts that Schering's presentation to its Board of Directors "explained that the payments represented lost revenue for the period Upsher stayed off the market." Pet. at 28 n.26. In fact, the presentation to the Board specifically informed the Board that Schering told Upsher-Smith "that any such deal should stand on its own merit independent of the settlement." Pet. App. at 198a. Schering's Board members testified expressly that they understood they were to evaluate the Niacor-SR license (and the bundle of other licenses) as a stand-alone deal, and that they did so. Pet App. at 199a.

continued litigation. Pet. App. at 75a-77a. In response, Schering called its own expert economist who testified that the Commission's theory was wrong; and that in order to determine whether a particular settlement is anticompetitive it is necessary to evaluate the strength of the underlying patent case. Pet. App. at 87a-89a.

Schering then introduced the expert testimony of an experienced patent litigator who had evaluated the objective strength of Schering's positions in both the Upsher-Smith and ESI patent cases. He testified that Schering's patent was valid and infringed; that Schering likely would have won both cases; and that the settlements reasonably reflected the strength of Schering's position in each case. *See* Pet. App. at 27a.[5]

The ESI Settlement

With regard to the ESI settlement, the Commission introduced almost no proof at all. The Commission called no fact witnesses to testify at trial about the ESI settlement, and the Commission's economic expert testified about the ESI case for only about fifteen minutes. Pet. App. at 261a. In its case, Schering presented expert testimony by an experienced patent litigator that Schering's patent case against ESI was very strong, and that the settlement's January 1, 2004 entry date reasonably reflected Schering's strong case. *See* Pet. App. at 27a. The Commission's trial counsel hired its own patent-litigator expert to review the record in the ESI patent case, *but he never testified about it*.

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[5] The Commission called its own patent-litigator expert. He testified about the Upsher-Smith patent case, but not about the ESI case. The Commission's opinion never mentions either Schering's or its own expert's testimony regarding the patent case.

4. The Decisions

The ALJ found that Schering's witnesses on the valuation issue were "credible and unrebutted," and that the Commission's trial counsel had failed to satisfy its conceded burden of proving that Schering's $60 million payment to Upsher-Smith was not a *bona fide*, fair-value payment for Niacor-SR (and the bundle of other products). Pet. App. at 316a-318a, 325a-326a, 340a. The ALJ also found that the Commission had failed to prove that either settlement yielded less competition than litigation or any available alternative settlement would have yielded. Pet. App. at 310a-311a. Accordingly, the ALJ dismissed the complaint in its entirety.

The Commission reversed. It found that the rights to Niacor-SR and other products were not "adequate" consideration for Schering's $60 million payment, thus refusing to credit the testimony of Schering's and Upsher-Smith's employees and Schering's expert witness on valuation. Pet. App. at 55a.[6] The Commission declined to credit this testimony even though (1) the Commission's staff had presented no fact witness to testify about the value of Niacor-SR; (2) the Commission had no expert testimony on the valuation issue to rely on; (3) the Commission did not observe any of the witnesses whose testimony it refused to believe; and (4) the Commission has no expertise of its own in valuing pharmaceutical products.[7]

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[6] The petition similarly disregards evidence that even the Commission's opinion acknowledged. For example, the petition baldly states that Upsher-Smith demanded a payment "to stay off the market," Pet. at 7, but even the Commission's opinion admits that from the outset Upsher-Smith sought a payment *and* early entry. Pet. App. at 97a.

[7] The author of the Commission's opinion has conceded that the Commission has no expertise in valuing licensing opportunities in the pharmaceutical industry: "[H]ow do we know whether the intellectual property acquired by the pioneer is genuinely worth the money paid or

Having overruled its own ALJ and concluded that there was a net "payment" from Schering to Upsher-Smith (i.e., a payment in excess of fair market value for Niacor-SR and the other Upsher-Smith licenses), the Commission turned to its antitrust analysis. First, it concluded that the "payments" did not render the settlements either *per se* violations of the antitrust laws, or "inherently suspect." Pet. App. at 80a. The Commission explicitly endorsed a rule of reason analysis. Pet. App. at 54a-55a. It did so because Schering has a patent, giving it the lawful right to exclude competitors from the market. Therefore, the Commission undertook to compare the exclusionary impact of the agreements with the lawful exclusionary effect of the patent. Pet. at 9.

However, the Commission explicitly declined directly to evaluate the exclusionary power of Schering's patent. Instead, the Commission concluded as a matter of theory that a payment would likely render the settlement agreement anticompetitive. Pet. App. at 76a-77a. The Commission treated the "payments" as shifting the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But in its opinion, the Commission never considered, or even mentioned, the evidence placed in the record by Schering that presumably would have addressed any burden Schering might have had; namely, the proof comparing the strength of Schering's patent case with the compromise entry dates in the settlement agreements.

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whether the whole side deal is simply a roundabout way of making otherwise suspect reverse payments? The difficulty here, of course, is similar to the difficulty the Commission would face in evaluating the merits of a patent dispute, a subject discussed above: the fact that we are not very well equipped to place a value on intellectual property." Commissioner Thomas B. Leary, "Antitrust Issues in the Settlement of Pharmaceutical Disputes, Part II," May 17, 2001 at 6.

A panel of the Court of Appeals for the Eleventh Circuit unanimously set aside the Commission's opinion and vacated its Order. After a thorough review of the whole record under the "substantial evidence" standard, the Court of Appeals found that the Commission's finding of fact on the valuation issue was not supported by substantial evidence. The Court of Appeals also faulted the Commission's almost exclusive reliance on the purported existence of a payment as the basis for its conclusion that the patent-litigation settlements were anticompetitive. Instead, the Court of Appeals held that a factual inquiry into the exclusionary power of Schering's patent was required. Because the Commission failed to engage in such an inquiry, the Court of Appeals set aside the Commission's Opinion. Pet. App. at 34a-35a.

REASONS FOR DENYING THE WRIT

The petition should be denied for the following reasons.

1. The Commission Lost the Schering/Upsher-Smith Case on a Dispositive Threshold Issue of Fact.

The great majority of the trial of this case was devoted to the question whether the $60 million payment from Schering to Upsher-Smith was fair value for the rights to Niacor-SR and the other products. The Commission conceded in its opinion that its entire legal analysis hinged on this "critical valuation issue." Pet. App. at 92a. And the Commission's staff had conceded at trial that "there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher." Pet. App. at 92a.

After a full trial on the fair value issue, the Commission's ALJ determined that the Respondents' "fact testimony . . . was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction." Pet. App. at 317a-318a. And the Court of Appeals found that the Commission's contrary finding of fact on its *de novo* review of the record was unsupported by any substantial evidence.

The finding by the Court of Appeals is on a pure issue of fact with significance to this case and this case only. It disposes of the Commission's challenge to the Schering/Upsher-Smith settlement, and there is no reason to review it.

2. The Schering/ESI Settlement Does Not Warrant Review.

The Commission's half-hearted challenge to the Schering/ESI settlement also does not warrant review. The Commission itself conceded in its own opinion that, with respect to the ESI settlement, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a.

The evidence that *was* introduced showed that the settlement resulted from fifteen months of court-supervised mediation. The small payment was needed to break an impasse in the negotiations, and it was urged on the parties by the U.S. Magistrate Judge as a way of resolving the case. The resulting settlement was fair to consumers as well as to the parties: the unrebutted evidence showed that the compromise entry date fairly reflected the strength of Schering's patent case. Under a rule of reason analysis—which the Commission says is the appropriate analysis—the

ESI settlement presents only a fact-specific case correctly resolved by the Court of Appeals.

3. The Court of Appeals Did Not Misapply the Standard of Review of Agency Fact Finding; and in Any Event the Misapplication of a "Properly Stated Rule of Law" Does Not Warrant Certiorari.

It is undisputed that the Court of Appeals properly stated the standard that courts of appeals must follow when reviewing agency fact finding. Thus, the Court of Appeals explained that:

> The FTC's findings of fact, "if supported by evidence, shall be conclusive." *This standard applies regardless whether the FTC agrees with the ALJ.* (emphasis added).

The Court of Appeals continued:

> *We are mindful that we do not review the record to draw our own conclusions* that we then measure against an administrative agency; rather, we must consider *all* of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed.

Pet. App. at 10a-12a (internal citations omitted) (emphasis added).

The Commission makes no claim that the Court of Appeals misstated the standard of review. Rather, the Commission complains that the Court of Appeals attached some weight to the ALJ's credibility determinations. But that is exactly what this Court has held a reviewing court of appeals ought to do. Thus, in *Universal Camera v. NLRB*, 340 U.S. 474, 496 (1950), this Court stated:

> [E]vidence supporting a conclusion [by the agency] may be less substantial when an impartial, experienced examiner who has *observed the witnesses and lived with the case* has drawn conclusions different from the [agency's] than when he has reached the same conclusion. (emphasis added).

And this Court continued,

> The significance of [the examiner's] report, of course, depends largely on the *importance of credibility* in the particular case.

Universal Camera, 340 U.S. at 496 (emphasis added).[8]

Credibility was very important in this case. If Respondents' witnesses on the valuation issue—who testified fully at trial—were believed, the Commission's challenge to the Upsher-Smith settlement would fail.

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[8] The Commission's petition omits any reference to these parts of the *Universal Camera* opinion.

In its opinion, the Court of Appeals correctly stated the applicable standard of review. The Commission is thus left to complain—with little or no basis—only that the Court of Appeals *misapplied* that standard in this particular case. Respondents strongly disagree. However, in either event, this Court's rules state that "a petition for certiorari is rarely granted when the asserted error consists of . . . misapplication of a properly stated rule of law." SUP. CT. R. 10.[9] This case is not one of those rare instances.

4. The Petition Overstates the Difference in Antitrust Analysis Between the Court of Appeals and the Commission.

The Commission overstates the extent to which the Court of Appeals' antitrust analysis differs from its own. There is indeed much common ground.

An agreement determining a potential competitor's entry into the market would be illegal *per se* if there were no patent. Both the Commission and the Court of Appeals agree about this. As the Commission explains: "The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is 'clearly anticompetitive,' and hence unlawful *unless excused by the lawful exercise of patent rights*." *See* Pet. at 13 (emphasis added). Similarly, the Court of Appeals explained that, if not for a patent, an

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[9] The Commission also complains that the Court of Appeals did not afford sufficient "deference" to the Commission's expertise. Pet. at 29. But the critical fact issue in this case was the valuation of Niacor-SR, a pharmaceutical product. And as noted above, the Commission has no expertise in valuing pharmaceutical products. This proposition was acknowledged by the author of the Commission's opinion, Commissioner Thomas B. Leary. *See supra* n.7.

agreement to allocate markets is "clearly anticompetitive." Pet. App. at 13a.

The Commission and the Court of Appeals also agree that a payment—if proved—would not make these settlements subject to *per se* treatment, because of the existence of Schering's patent. Pet. at 9. Thus, the Commission explains that it "determined that per se condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose." *Id.* Similarly, the Court of Appeals explained: "In the context of patent litigation . . . the anticompetitive effect [of the agreement] may be no more broad than the patent's own exclusionary power." Pet. App. at 13a.

Finally, the Commission and the Court of Appeals agree that the appropriate antitrust analysis must involve a comparison of the exclusionary effect of the settlement with the lawful exclusionary power of Schering's patent. As the Commission states, it believes it should conduct precisely such an analysis in this case, comparing "the exclusionary impact of the agreements in relation to that of the patent itself." Pet. at 9. Similarly, the Court of Appeals explained that it was comparing "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreement exceeds the scope; and (3) the resulting anticompetitive effects." Pet. App. at 17a.[10]

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[10] The Commission describes the Court of Appeals' statement that the court would apply neither traditional rule of reason nor *per se* analysis as a "startling premise," Pet. at 11, and suggests that this is a sharp point of difference between the Commission's approach and the Court of Appeals'. It is not. If anything, it is a difference in label, not analysis. The Court of Appeals' point is that a traditional rule of reason analysis would examine solely the market effects of generic entry. That, however, is not the pertinent inquiry here. Everyone already knows that generic entry will bring lower prices. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003), *cert. denied*

Officials of the Antitrust Division of the U.S. Department of Justice have similarly rejected *per se* treatment for patent settlement payments because of the importance of the exclusionary power of patents. For example, in 2003, the then-Acting Assistant Attorney General for the Antitrust Division explained:

> [A]ssessing the competitive significance of settlements often depends on an evaluation of the underlying strength of patent rights. If a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder. If a patent is invalid or not infringed, then there should be no impediment to competitive entry whatsoever. The problem is that we have no way definitively to know which situation applies *without evaluating the underlying IP rights*, a task that is outside our core expertise as antitrust enforcers.[11]

Then-Assistant Attorney General Pate reiterated this view in a recent speech. Noting the fact that the Court of Appeals *in this case* had ruled just "months ago," Mr. Pate explained that antitrust liability is difficult to assess:

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sub nom. Walgreen Co. v. Abbott Labs., No. 03-1178 (Oct. 12, 2004). The important inquiry here, according to the Court of Appeals, is whether the settlement agreement's exclusionary effects exceed the legitimate exclusionary power of the patent. *See* Pet. App. at 16a; *Valley Drug*, at 344 F.2d 1294, 1311 n.27. The Commission accepts this as the relevant inquiry, stating that it "considered the exclusionary impact of the agreements in relation to that of the patent itself." Pet. at 9. The Commission calls this inquiry a rule of reason inquiry, and the Court of Appeals does not. But it is the same inquiry.

[11] R. Hewitt Pate, Acting Assistant Attorney General, Antitrust Division, "*Antitrust and Intellectual Property*," January 24, 2003 (emphasis added).

> unless one knows whether the patent owner could have won an infringement claim. If the patent is valid, all entry before its expiration is a competitive "gift," but if it is invalid, any delay in entry due to threatened patent enforcement is a competitive harm.[12]

District courts have expressed similar views. *See, e.g., Asahi Glass Co. Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J. sitting by designation) (doubting correctness of theory that payments render settlements anticompetitive regardless of patent merits because "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent"); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 540 (E.D.N.Y. 2005) (settlement with payments not anticompetitive if within scope of patent claims).

Thus, the Commission, the Court of Appeals and the Department of Justice agree on the basic framework for analyzing settlements of patent infringement suits that include payments. The problem in this case, however, arose when the Commission *implemented* that framework.

In its opinion in this case, the Commission relied solely on the purported fact of a payment, finding that the payment meant, as a matter of theory, that the settlement was anticompetitive. Pet. App. at 76a-77a ("[I]t is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.").

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[12] R. Hewitt Pate, Assistant Attorney General, Antitrust Division, *"Competition and Intellectual Property in the U.S.: Licensing Freedom and the Limits of Antitrust,"* June 3, 2005.

The Commission then shifted the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But the Commission ignored the proof Respondents had placed in the record to meet that burden: proof comparing the strength of Schering's patent case to the compromise entry dates in the settlement agreements.

The problem, thus, was that the Commission's implementation of its announced rule of reason framework turned out in practice to be no different from the *per se* rule it purported to reject.

5. The Commission's Statements About the Real World Dangers of Patent Settlement Are Suspect.

The Commission does not assert that there is any conflict among the circuits on the issues presented by this case. The Commission states that the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, No. 03-799 (October 12, 2004), represents a "different approach" from that of the Eleventh Circuit in this case, but the Commission expressly disagrees with the Sixth Circuit's approach. Pet. at 23. Moreover, as the Commission told this Court a year ago, there is no "square conflict" between the circuits because of dispositive factual differences between the *Cardizem/Andrx* case and the Eleventh Circuit's decision in a similar pharmaceutical patent case, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).[13] *Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL

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[13] The Court of Appeals' decision in this case expressly follows its prior *Valley Drug* decision. Pet. App. at 12a-17a.

1562075 (July 2004), at *11. Nothing has changed in that regard.

Furthermore, the Commission and the Solicitor General urged in their opposition to certiorari last term in *Cardizem/Andrx* that "[s]ettlements with reverse payments in an amount far exceeding litigation costs . . . appear to be rare outside the Hatch-Waxman context;" and that Congress' 2003 Amendments to the Hatch-Waxman Act reduced the risk of anticompetitive settlements in the pharmaceutical arena. *See* U.S. Br., 2004 WL 1562075, at *15-*19. Accordingly, the Commission urged that certiorari was not warranted.

The Commission and the Solicitor General also noted that Congress' 2003 amendments to Hatch-Waxman requiring mandatory review of all pharmaceutical patent-litigation settlements by the antitrust agencies counseled against certiorari in *Cardizem/Andrx*. The Commission's first annual report on this mandatory review of such settlements, published in January 2005, substantiates this view. Thus, the Commission states: "legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise." Pet. at 22. Indeed, the Commission's January 2005 report goes further in stating that settlements involving payments to the alleged infringer are not a pressing issue:

> The structure of brand-generic settlements has changed over time in that *settlements after 1999 do not appear to include a payment from the brand to the generic in exchange for the generic's agreement not to market its product*. . . . In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such

> payments. *Since that time, the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product.*[14]

It may well be that the Commission's actions in this case and others have had an *in terrorem* effect on subsequent settlements.

Despite its January 2005 report, the Commission speculates that future settlements may nonetheless raise antitrust concerns, and absent this Court's review, "any substantial pharmaceutical company involved in a further case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit." Pet. at 24. The Commission's conjecture is unfounded, however. First, the Commission is free to bring an action in any district court in which a pharmaceutical company conducts business. 15 U.S.C. § 45(m) (2005). Second, private plaintiffs may also bring suit against pharmaceutical companies in any district in which such pharmaceutical company conducts business. 28 U.S.C. §1391(b) (2005). Third, the Commission could bring its cases in a manner consistent with the Eleventh Circuit's decision. A recent decision by the Eleventh Circuit shows that its decision in this case does not portend the death-knell of antitrust cases against pharmaceutical patent settlements, as the Commission speculates. *See Andrx Pharmaceuticals,*

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[14] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B] (emphasis added).

Inc. v. Elan Corp., et al., __ F.3d __, 2005 WL 2061009 (11th Cir. Aug. 29, 2005) (refusing to dismiss antitrust complaint against pharmaceutical patent settlement: complaint successfully plead antitrust violation consistent with the Court of Appeals' *Schering-Plough* decision).

Finally, the Commission asserts that this Court's review is necessary because the Court of Appeals' decision will thwart congressional policy to encourage entry of generic pharmaceuticals. As the Commission concedes, however, the Hatch-Waxman Act attempts to balance its goal of encouraging generic entry with an equally important goal of "fully protecting legitimate patent claims." Pet. at 3. The Court of Appeals' decision in this case accommodates this balance. For example, Schering's settlement with Upsher-Smith split the remaining life of Schering's patent in half, and allowed generic entry five years *before* the expiration of Schering's patent. Without comparing the settlement to the exclusionary potential of Schering's patent, it is impossible to know whether generic entry was delayed or accelerated. In fact, the evidence adduced at trial established that, based on the strength of Schering's patent case, entry was likely accelerated.

As the Commission argued a year ago, this Court's review is not warranted. Nothing has changed to alter that conclusion.

CONCLUSION

For all of the foregoing reasons, the petition should be denied.

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No. ___

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

[PUBLISH]

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-10688

Agency No. FTC 9297

SCHERING-PLOUGH CORPORATION,
UPSHER-SMITH LABORATORIES, INC.,
A MINNESOTA CORPORATION HAVING ITS PRINCIPAL
PLACE OF BUSINESS IN MINNESOTA,
PETITIONERS,

VERSUS

FEDERAL TRADE COMMISSION,
RESPONDENT.

Petitions for Review of a Decision of the
Federal Trade Commission

(March 8, 2005)

Before DUBINA and FAY, Circuit Judges, and
GOLDBERG *, Judge.

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* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

FAY, Circuit Judge:

Pharmaceutical companies Schering-Plough Corp. and Upsher-Smith Laboratories, Inc. petition for review of an order of the Federal Trade Commission ("FTC") that they cease and desist from being parties to any agreement settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time. The issue is whether substantial evidence supports the conclusion that the Schering-Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(c). We have jurisdiction pursuant to 15 U.S.C. § 45(c), and, for the reasons discussed below, we grant the petition for review and set aside and vacate the FTC's order.

I. Factual Background

A. The Upsher Settlement

Schering-Plough ("Schering") is a pharmaceutical corporation that develops, markets, and sells a variety of science-based medicines, including antihistamines, corticosteroids, antibiotics, anti-infectives and antiviral products. Schering manufactures and markets an extended-release microencapsulated potassium chloride product, K-Dur 20,which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-

Dur 20, patent number 4,863,743 (the "'743 patent"). The '743 patent expires on September 5, 2006.[1]

In late 1995, Upsher-Smith Laboratories ("Upsher"), one of Schering's competitors, sought Food and Drug Administration ("FDA") approval to market Klor Con M20 ("Klor Con"), a generic version of K-Dur 20.[2] Asserting that Upsher's product

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[1] Schering also markets another version of this product, K-Dur 10, the coating of which is also covered by the '743 patent. The difference between the two is dosage: K-Dur 20 contains twice as much potassium as K-Dur 10. This lawsuit only involves K-Dur 20.

The '743 patent claims a pharmaceutical dosage unit in tablet form for oral administration of potassium chloride. The tablet contains potassium chloride crystals coated with a cellulose-type material. The novel feature in the '743 patent is the viscous coating, which is applied to potassium chloride crystals. The coating provides a sustained-release delivery of the potassium chloride.

[2] The FDA must approve any new drug before it can be marketed or sold in the United States. Previously, applications for FDA approval proceeded under a new drug application ("NDA"). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub.L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application ("ANDA") to bring generic drugs to the market.

The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch-Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bio-equivalent to the already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a "Paragraph IV certification." The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).

was an infringing generic substitute, Schering sued for patent infringement. K-Dur 20 itself was the most frequently prescribed potassium supplement, and generic manufacturers such as Upsher could develop their own potassium-chloride supplement as long as the supplement's coating did not infringe on Schering's patent.

In 1997, prior to trial, Schering and Upsher entered settlement discussions. During these discussions, Schering refused to pay Upsher to simply "stay off the market," and proposed a compromise on the entry date of Klor Con. Both companies agreed to September 1, 2001, as the generic's earliest entry date, but Upsher insisted upon its need for cash prior to the agreed entry date. Although still opposed to paying Upsher for holding Klor Con's release date, Schering agreed to a separate deal to license other Upsher products. Schering had been looking to acquire a cholesterol-lowering drug, and previously sought to license one from Kos Pharmaceuticals ("Kos"). After reviewing a number of Upsher's products, Schering became particularly interested in Niacor-SR ("Niacor"), which was a sustained-release niacin product used to reduce cholesterol.[3]

Upsher offered to sell Schering an exclusive license to market Niacor worldwide, except for North America. The parties executed a confidentiality agreement in June 1997, and Schering received licenses to market five Upsher products, including Niacor. In relation to Niacor, Schering received a data package, containing the results of Niacor's clinical studies.

As part of its ANDA, Upsher certified that Schering's patent was either invalid or that Upsher did not infringe on that patent. When Schering brought suit, the thirty-month delay was activated.

[3] Schering's focus on Niacor is consistent with its previous attempt to purchase the rights to Niaspan, another sustained-release niacin product, which Kos was in the process of developing during this time. Negotiations between Kos and Schering broke down several months before Upsher offered Niacor to Schering.

The cardiovascular products unit of Schering's Global Marketing division, headed by James Audibert ("Audibert") evaluated Niacor's profitability and effectiveness.

According to the National Institute of Health, niacin was the only product known to have a positive effect on the four lipids related to cholesterol management. Immediate-release niacin, however, created an annoying – but innocuous – side effect of "flushing," which reduced patient compliance. On the other hand, previous versions of sustained-release niacin supplements, like Niacor, had been associated with substantial elevations in liver enzyme levels.

Schering knew of the effects associated with niacin supplements, but continued with its studies of Niacor because it had passed the FDA's medical review and determined that it would likely be approved. More important, the clinical trials studied by Audibert demonstrated that Niacor reduced the flushing effect to one-fourth of the immediate-release niacin levels and only increased liver enzymes by four percent, which was generally consistent with other cholesterol inhibitors. Based on this data, Audibert constructed a sales and profitability forecast, and concluded that Niacor's net present value at that time would be between $245-265 million.

On June 17, 1997, the day before the patent trial was scheduled to begin, Schering and Upsher concluded the settlement. The companies negotiated a three-part license deal, which called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering's board approved of the licensing transaction after determining the deal was valuable to Schering. This estimation corresponds to the independent valuation that Schering completed in relation to Kos' Niaspan, a substantially similar product to Niacor. That evaluation fixed Niaspan's net present value between $225-265 million.

The sales projections for both the Kos and Upsher products are substantially similar. Raymond Russo ("Russo") estimated Niaspan (Kos' supplement) sales to reach $174 million by 2005 for the U.S. market. Comparably, and more conseratively, Audibert predicted Niacor (Upsher's supplement) to reach $136 million for the global market outside the United States, Canada, and Mexico, which is either equal to or larger than U.S. market alone.[4]

After acquiring the licensing rights to Niacor, Schering began to ready its documents for overseas filings. In late 1997, however, Kos released its first-quarter sales results for Niaspan, which indicated a poor performance and lagging sales. Following this announcement, Kos' stock price dramatically dropped from $30.94 to $16.56, and eventually bottomed out at less than $6.00. In 1998, with Niaspan's disappointing decline as a precursor, Upsher and Schering decided further investment in Niacor would be unwise.

B. The ESI Settlement

In 1995, ESI Lederle, Inc. ("ESI"), another pharmaceutical manufacturer, sought FDA approval to market its own generic version of K-Dur 20 called "Micro-K 20."[5] Schering sued ESI in United States District Court, and, as part of the pretrial process, the trial judge prompted the parties to engage a court-supervised mediation, pursuant to the Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991). The trial court appointed U.S.

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[4] Indeed, there is the indication of some internal independence between Schering's evaluation of Niaspan and Niacor, as two different teams examined the products and arrived at similar estimates.

[5] On December 22, 1995, ESI submitted an ANDA to the FDA that reference K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. On December 29, 1995, ESI notified Schering of this certification containing data from a study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20's tablets.

Magistrate Judge Thomas Rueter ("Judge Rueter") to mediate the fifteen-month process, which resulted in nothing more than an impasse.

Finally, in December 1997, Schering offered to divide the remaining patent life with ESI and allow Micro-K 20 to enter the market on January 1, 2004 – almost three years ahead of the patent's September 2006 expiration date.[6] ESI accepted this offer, but demanded on receiving some form of payment to settle the case. At Judge Rueter's suggestion, Schering offered to pay ESI $5 million, which was attributed to legal fees, however, ESI insisted upon another $10 million. Judge Rueter and Schering then devised an amicable settlement whereby Schering would pay ESI up to $10 million if ESI received FDA approval by a certain date. Schering doubted the likelihood of this contingency happening, and Judge Rueter intimated that if Schering's prediction proved true, it would not have to pay the $10 million.[7] The settlement was signed in Judge Rueter's presence on January 23, 1998.[8]

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[6] There was also a side agreement in this settlement that provided for a payment of $15 million in return for the right to license generic enalpril and buspirone from ESI..

[7] ESI provided Schering with information related to the Micro-K 20's current approval status. The summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version. The primary concern was ESI's bioequivalence study, which had been performed in 1989. The FDA found five different deficiencies with regard to that study, and ESI did not respond to those deficiencies until May 1997. ESI then began a new bioequivalence study in December 1997.

[8] Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.

C. The FTC Complaint

On March 30, 2001, more than three years after the ESI settlement, and nearly four years after the Schering settlement, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation ("AHP"). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The complaint also charged that Schering monopolized and conspired to monopolize the potassium supplement market.[9]

II. Procedural History

The Complaint was tried before an Administrative Law Judge (ALJ) from January 23, 2002 to March 28, 2002. Numerous exhibits were admitted in evidence, and the ALJ heard testimony from an array of expert witnesses presented by both sides. In his initial decision, the ALJ found that both agreements were lawful settlements of legitimate patent lawsuits, and dismissed the complaint. Specifically, the ALJ ruled that the theories advanced by the FTC, namely, that the agreements were anticompetitive, required either a presumption of (1) that Schering's '743 patent was invalid; or (2) that Upsher's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact. Moreover, the ALJ noted that Schering's

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[9] On October 12, 2001, the Complaint against AHP was withdrawn to consider a proposed consent agreement. The FTC approved a final consent order on April 2, 2002. AHP was not a party to either the trial before the ALJ or any subsequent proceedings, and is not a party to this appeal. The legality of the Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

witnesses went unrebutted by FTC complaint counsel, and credibly established that the licensing agreement with Upsher was a "bona-fide arm's length transaction."

The ALJ further found that the presence of payments did not make the settlement anticompetitive, per se. Rather, the strength of the patent itself and its exclusionary power needed to be assessed. The initial decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant potassium chloride supplement market.

The FTC's complaint counsel appealed this decision to the full Commission. On December 8, 2003, the Commission issued its opinion, reversing the ALJ's initial decision, and agreeing with complaint counsel that Schering's settlements with ESI and Upsher had violated the FTC Act and the Sherman Act. Although it refrained from ruling that Schering's payments to Upsher and ESI made the settlements per se illegal, the Commission concluded that the quid pro quo for the payment was an agreement to defer the entry dates, and that such delay would injure competition and consumers.

In contrast to the ALJ's inquiry into the merits of the '743 patent litigation, the Commission turned instead to the entry dates that "might have been" agreed upon in the absence of payments as the determinative factor. Despite the Commission's assumption that the parties could have achieved earlier entry dates via litigation or non-monetary compromises, it also acknowledged that the settled entry dates were non-negotiable. Upon review of the settlement payments, the Commission determined that neither the $60 million to Upsher nor the $30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA

approval of its generic.[10] Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a "simple compromise" to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties need not worry about a later antitrust attack. Neither of the Schering agreements fit this caveat, and Schering and Upsher timely petition for review.

III. Standard of Review

We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. 15 U.S.C. § 45(c); see Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354 (11th Cir. 1988); Oiin Corp. v. FTC, 986 F.2d 1295 (9th Cir. 1993). The FTC's findings of fact, "if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). This standard applies regardless whether the FTC agrees with the ALJ. Thiret v. FTC, 512 F.2d 176, 179 (10th Cir. 1975). We may, however, examine the FTC's findings more closely where they differ from those of the ALJ. Id.; California Dental Association v. FTC, 128 F.3d 720, 725 (9th Cir.1997), rev'd on other grounds, 526 U.S. 756 (1990); see also ITT Continental Baking Co. v. FTC, 532 F.2d 207, 219 (2d Cir. 1976); American Cyanamid Co. v. FTC, 363 F.2d 757, 772-73 (6th Cir. 1966). "Substantial evidence is more than a mere

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[10] The contradictory nature of the Commission's opinion is exemplified by its assessment of the ESI settlement. Although the Commission found the payment to be unjustified and in violation of the law, it simultaneously explained that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence."

scintilla," and we require "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938); Consolo v. Federal Maritime Commission, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966); see NLRB v. Gimrock Constr., Inc., 247 F.3d 1307, 1309 (11th Cir. 2001). While we afford the FTC some deference as to its informed judgment that a particular commercial practice violates the FTC Act, we review issues of law de novo. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 454, 106 S.Ct. 2009, 2015-16, 90 L.Ed.2d 445 (1986).

In their arguments, the parties urge that Universal Camera provides the yardstick by which to measure the evidence at issue. Indeed, in 1951, the Supreme Court clarified the substantial evidence standard for reviewing an administrative agency's decision. Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88, 95 L. Ed. 456, 71 S. Ct. 456 (1951). In Universal Camera, the ALJ found an employee was lawfully discharged for insubordination rather than his appearance at an NLRB proceeding. The factual testimony directly conflicted, and the ALJ's finding clearly relied on a credibility determination. The Board reversed the holding. On judicial review, the court of appeals hesitated to consider the ALJ's initial ruling because the Administrative Procedure Act gave the Board "all the powers it would have had in making the initial decision." 5 U.S.C. § 557(b). Thus, the Second Circuit affirmed the Board's decision. The Supreme Court disagreed, and held that the plain language of the statute required a review of the record as a whole, which included the ALJ's decision. Universal Camera, 340 U.S. at 493.

Although Universal Camera involved the NLRB, and not the FTC, the results are applicable here. When we review a jury verdict, we ignore all evidence contrary to the verdict and then draw every reasonable inference in favor of the verdict

from the remaining evidence. In the administrative setting, however, Universal Camera dictates that "the substantiality of the evidence must take into account whatever in the record fairly detracts from its weight." Id. at 488. We are mindful that we do not review the record to draw our own conclusions that we then measure against an administrative agency; rather, we must consider all of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed. Id.

IV. Discussion

The question remains whether the Commission's conclusions are legally sufficient to establish a violation of the Sherman Act and the FTC Act--that is, whether Schering's agreements with Upsher and ESI amount to an "unreasonable" restraint of trade. In Valley Drug, this Court stated that the "ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1303-04 (11th Cir. 2003) (citing NCAA v. Bd. of Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984)). We wrote that the focus of antitrust analysis should be on "what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties." Valley Drug, 344 F.3d at 1304.

Valley Drug involved an interim se[illegible]ement agreement between a patent-holding pharmaceutical company and its potential generic competitor. Under the agreement, the patent holder paid the generic manufacturer $4.5 million per month to

keep its product off the market until resolution of the underlying patent infringement suit. The lower court determined that the payments amounted to a per se violation of antitrust laws. See In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340 (S.D. Fla. 2000). We reversed that decision, and concluded that monetary payments made to an alleged infringer as part of a patent litigation settlement did not constitute a per se violation of antitrust law. Valley Drug, 344 F.3d at 1309.

Although we acknowledged in Valley Drug that an agreement to allocate markets is "clearly anticompetitive," resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent. Id. at 1304. We recognized the effect of agreements that employ extortion-type tactics to keep competitors from entering the market. In the context of patent litigation, however, the anticompetitive effect may be no more broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would "obviously chill such settlements." Id. at 1309.

Both the ALJ and the Commission analyzed the Schering agreements according to the rule of reason analysis, albeit under two different methodologies. To the contrary, the district court in Valley Drug approached the agreements in that case from the perspective of whether they were a per se violation of antitrust laws. Under the Supreme Court's guidance, an alleged restraint may be found unreasonable either because it fits within a category of restraints that has been held to be "per se" unreasonable, or because it violates the so-called "Rule of Reason."[11] The rule of reason tests "'whether the restraint

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[11] The majority of antitrust claims are analyzed under the rule of reason. State Oil Co. v. Khan, 522 U.S. 3, 20 (1997). Courts generally determine the reasonableness of a particular agreement by reference to the surrounding facts and circumstances under the rule of reason. Generally, a per se analysis is applied only in limited circumstances, and after experience and

imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.'" FTC v. Indiana Federation of Dentists, 476 U.S. 447, 457, 106 S.Ct. 2009, 2017, 90 L.Ed.2d 445 (1986) (quoting Chicago Board of Trade v. United States, 246 U.S. 231, 238, 385 S.Ct. 232, 244 (1918)).[12]

Both the ALJ's initial decision and the Commission's opinion rejected the per se approach, and instead employed the rule of reason. The traditional rule of reason analysis requires the factfinder to "weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49, 97 S.Ct. 2549, 2557, 53 L.Ed.2d 568 (1977). The plaintiff bears an initial burden of demonstrating that the alleged agreement produced adverse, anti-competitive effects within the relevant product and geographic markets, i.e., market power. See FTC

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pattern establish that a particular class of restraint is manifestly anticompetitive. Broadcast Music, Inc. v. Columbia Broad. Sys,, Inc. U.S. 1, 9 (1979). Essentially, the per se rule should only be employed when the conduct has "pernicious effect on competition" and "lack[s] ... any redeeming virtue." Continental T.V. Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 (1977).

[12] By and large, the construction of the rule of reason inquiry has remained unaltered since the Supreme Court first articulated it in Chicago Board of Trade v. United States, 246 U.S. 231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683 (1918):

> [T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

v. Indiana Federation of Dentists, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986).[13]

Once the plaintiff meets the burden of producing sufficient evidence of market power, the burden then shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective. A restraint on competition cannot be justified solely on the basis of social welfare concerns. See, e.g., National Society of Professional Engineers v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978); Indiana Dentists, 476 U.S. at 463, 106 S.Ct. at 2020. In rebuttal then, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective. Bhan v. NME Hospitals, Inc., 929 F.2d 1404, 1413 (9th Cir.), cert. denied, 502 U.S. 994, 112 S.Ct. 617, 116 L.Ed.2d 639 (1991).

In the present case, the Commission emphasized that its rule of reason standard required a methodology different from that set out by the ALJ's initial decision. The Commission chided the ALJ's approach – which evaluated the strength of the patent, defined the relevant geographic and product markets, calculated market shares, and then drew inferences from the shares and other industry characteristics – as an inappropriate manner of analyzing the competitive effects of the parties' activities. Instead, the Commission's rule of reason dictated application of the Indiana Federation exception, in that complaint counsel need not prove the relevant market. See 476 U.S. at 460-61. Rather, the FTC was only required to show a detrimental market effect. Thus, under the Commission's

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[13] Indiana Dentists noted an exception to the burden of proving market power: "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.' " 476 U.S. at 460-61 7 (citing P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

standard, once the FTC met the low threshold of demonstrating the anticompetitive nature of the agreements, it found that Schering and Upsher did not sufficiently establish that the challenged activities were justified by procompetitive benefits. Despite the appearance that it openly considered Schering and Upsher's procompetitive affirmative defense, the Commission immediately condemned the settlements because of their absolute anti-competitive nature, and discounted the merits of the patent litigation. It would seem as though the Commission clearly made its decision before it considered any contrary conclusion.

We think that neither the rule of reason nor the per se analysis is appropriate in this context. We are bound by our decision in Valley Drug where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. 344 F.3d 1294, 1311 n. 27.[14] By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. "What is required here is an analysis of the extent to which antitrust liability

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[14] On remand, the district court in Valley Drug still applied a per se analysis, and found those agreements to be illegal. See In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005). We note that the case at bar is wholly different from Valley Drug. The critical difference is that the agreements at issue in Valley Drug did not involve final settlements of patent litigation, and, moreover, the Valley Drug agreements did not permit the generic company to market its product before patent expiration. On remand, the district court emphasized that the "[a]greement did not resolve or even simplify Abbott's patent infringement action ... to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided." In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005). Given these material distinctions, the same analysis cannot apply.

might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects." Id. Therefore, in line with Valley Drug, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. Valley Drug, 344 F.3d at 1312.[15]

A. The '743 Patent

"A patent shall be presumed valid." 35 U.S.C. § 282. See e.g., Doddridge v. Thompson, 22 U.S. 469, 483 (1824) (holding that a patent is presumed valid until the contrary is shown); Sure Plus Mfg. Co. v. Kobrin, 719 F.2d 1114, 1117 (11th Cir. 1983) ("Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office."). Engrafted into patent law is the notion that a patent grant bestows "the right to exclude others from profiting by the patented invention." Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176 (1980); see Valley Drug, 344 F.3d at 1304 ("A patent grants its owner the lawful right to exclude others."). Thus, the Patent Act essentially provides the patent owner

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[15] The Commission wrote that it would neither address the exclusionary power of Schering's patent nor compare the patent's scope to the exclusionary effect of the settlements. Rather, the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements with both ESI and Schering, resulting in earlier entry dates: "we cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact we make neither assumption, but focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement."

"with what amounts to a permissible monopoly over the patented work." Telecom Technical Services Inc. v. Rolm Co., 388 F.3d 820, 828 (11th Cir. 2004) (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969)). The Patent Act also explicitly allows for the assignability of a patent; providing the owner with a right to "grant or convey an exclusive right under his application for patent...to the whole or any specified part of the United States." 35 U.S.C. § 261.

By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent. Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. Simpson v. Union Oil Co., 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964). (Patent laws "are in pari materia with the antitrust laws and modify them pro tanto (as far as the patent laws go)."). Therefore, a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work. Valley Drug, 344 F.3d at 1305.

A patent gives its owner the right to grant licenses, if it so chooses, or it may ride its wave alone until the patent expires. Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940). What patent law does not do, however, is extend the patentee's monopoly beyond its statutory right to exclude. Mallinckrodt, Inc. v. Medipart, Inc. 976 F.2d 700, 708 (Fed.Cir. 1992); see also, United States v. Singer Mfg. Co., 374 U.S. 174, 196-197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) ("[B]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the

general law.... [T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). If the challenged activity simply serves as a device to circumvent antitrust law, then that activity is susceptible to an antitrust suit. Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F.Supp.2d 986, 991 (N.D. Ill. 2003), In Asahi, Judge Posner gave an illustrative example of when certain conduct transcends the confines of the patent:

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices--masks--for fixing prices, in violation of antitrust law.

Id.

It is uncontested that potassium chloride is the unpatentable active ingredient in Schering's brand-name drug K-Dur 20. Schering won FDA approval in 1986 to sell its K-Dur 20 tablets. Under the Hatch-Waxman scheme, in order for Upsher and ESI to obtain FDA approval to market their generic versions of an approved drug product like K-Dur 20, they simply needed to demonstrate that the drugs were bioquivalent, i.e., that the "active ingredient of the new drug is the same as that of the listed drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I).[16] K-Dur 20's uniqueness, and hence the reason for a patent, is the

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[16] In fact, Upsher received final FDA approval to market its Klor-Con generic version in November 1998. ESI followed suit, gaining FDA approval for Micro-K 20 in June 1999.

time-release capsule that surrounds the potassium chloride. Because the patent only covers the individualized delivery method (the sustained-release formula), and not the active ingredient itself, it is termed a "formulation" patent.

No one disputes that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. Nor is there any dispute that Schering's agreement with Upsher gave it a license under the '743 patent to sell a microencapsulated form of potassium chloride more than five years before the expiration of the '743 patent.[17] Likewise, ESI gained a license under the '743 patent to sell its microencapsulated version more than two years before the '743 patent expired. Perhaps most important, and which the ALJ duly noted, is that FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006. This reinforces the validity and strength of the patent.

Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a quid pro quo arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market, there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were "shams." Additionally, without any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product. Therefore, the proper analysis now turns to whether there is substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent. Valley Drug, 344 F.3d at 1306; see also In re Ciprofloxacin

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[17] Upsher began selling Klor Con M20 on September 1, 2001.

Hydrochloride Antitrust Litig., 261 F.Supp. 2d 188, 196 (E.D.N.Y. 2003).[18]

B. The Scope of Schering's Agreements

1. The Upsher Settlement

The FTC's complaint characterized the agreements at the center of this contest as "horizontal market allocation agreements," whereby Schering reserved its sales of K-Dur 20 for several years, while Upsher and ESI refrained from selling their generic versions of K-Dur 20 during that same time period. Adding to the FTC's ire is the presence of "reverse payments," represented by settlement payments from the patent owner to the alleged infringer. The Commission ruled that the coupling of reverse payments with an agreement by the generics not to enter the market before a particular date, "raise[d] a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry." Slip. Op. at 29.

In the context of Schering's settlement with Upsher, the FTC argues that the $60 million payment from Schering to Upsher was not a bona fide royalty payment under the licenses Schering obtained for Niacor and five other Upsher products. Instead, according to the FTC, the royalty payments constituted payoffs to delay the introduction of Upsher's generic. The FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay.

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[18] It is patently obvious that the Commission's opinion did not employ this analysis; preferring, instead, to proceed through its laborious rule of reason framework, eventually branding the challenged restraints to be illegal horizontal market allocation agreements. The Commission was ostensibly silent with regard to the '743 patent, yet it cavalierly dismissed our holding in Valley Drug, stating that a determination on the merits of the underlying patent disputes was "not supported by law or logic."

The trial before the ALJ covered 8,629 pages of transcript, involved forty-one witnesses, and included thousands of exhibits. The trial revealed that Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225-265 million. Upsher itself had invested significant time and financial resources in Niacor. Moreover, Schering had a long-documented and ongoing interest in licensing an extended-release niacin product, as evidenced by its efforts to acquire Niaspan from Kos Pharmaceuticals.

Evidence at trial also demonstrated that the personnel who evaluated Niaspan's potential were unaware of the ongoing litigation between Upsher and Schering, and had little, if any, incentive to inflate Niacor's value. Indeed, many of the estimates in conjunction with the Niacor evaluation traced the independent conclusions of the team that evaluated Niaspan. Schering's witnesses corroborated the documentary evidence, and the ALJ found the $60 million payment to Upsher to be a bona fide fair-value payment.

The Commission chose to align its opinion with the two witnesses presented by the FTC. One witness, Dr. Nelson Levy ("Levy") was proffered as an expert in pharmaceutical licensing and valuation. He concluded that the $60 million payment was "grossly excessive," and that Schering's due diligence in evaluating Niacor fell astonishingly short of industry standards. Levy cited Upsher and Schering's post-settlement behavior, as proof of the agreement's artificial nature. We are troubled by Levy's testimony. Interestingly, Levy arrived at his conclusions without performing a quantitative analysis of Niacor or any of the other Upsher products licensed by Schering. Additionally, Levy lacked expertise in the area of cholesterol-lowering drugs and niacin supplements. Finally, Levy's unpersuasive appraisal of the post-settlement behavior blatantly ignored the parties' ongoing communications and the fact that the niacin market essentially bottomed out. Although the Commission's opinion does not

state that it in relying on Levy's testimony, it curiously mirrors each of Levy's conclusions.

The FTC also offered Professor Timothy Bresnahan ("Bresnahan") to prove that Schering's payment was not for the Niacor license. While Bresnahan neither challenged Niacor's sales projections nor discounted its economic value, Bresnahan nonetheless opined that the payment was for Upsher's delayed entry, and not Niacor. Bresnahan based his conclusions on his interpretation of the parties' subjective incentives to trade a payment for delay. Bresnahan specifically pointed to Schering's failed transactions with Kos and the lack of other competitors vying for Niacor as evidence that the payment was not connected to the license.

Like the Levy testimony, the Commission did not expressly adopt Bresnahan's theories, but his rationale and the Commission's conclusions became one and the same. The Commission is quite comfortable with assenting to Bresnahan's rather amorphous "incentive" theory despite its lack of empirical foundation.[19] Unfortunately, Bresnahan's so-called incentives do not rise to the level of legal conclusions. We understand that certain incentives may rank high in these transactions, but it also true that the possibility of an outside impetus often lays dormant. The simple presence of economic motive weighs little on the scale of probative value. See Serfecz v. Jewel Food Stores, 67 F.3d 591, 600-01 (7th Cir. 1995) ("The mere existence of mutual economic advantage, by itself, does not tend to exclude the possibility of independent,

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[19] While the Commission's opinion conspicuously notes that it does not "adopt his terminology," it nonetheless endorses Bresnahan's incentive analysis: "We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences."

legitimate action and supplies no basis for inferring a conspiracy.").

The ALJ rejected the FTC's experts, concluding that testimony from Schering's witnesses "provides direct evidence that the parties did not exchange money for delay." The Commission disagreed, and determined that Niacor was not worth $60 million. To prove its point, the Commission relied on somewhat forced evidence: (1) the unconvincing fact that doctors gave Kos' niacin product mixed reviews, causing Schering to value those profits at an apparently contemptible $254 million; (2) the meretricious argument that Schering's personnel did not adequately assess Niacor's safety;[20] (3) the Commission's questionable non-expert opinion that Schering should have done more due diligence;[21] (4) the Commission's belief that the European market – where Schering held the Niacor license – for a niacin product was less desirable than the U.S. market;[22] and (5) Schering's post-settlement decision to

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[20] In his testimony before the ALJ, Dr. Levy asserted that Niacor was toxic to the liver and criticized Schering for not taking liver biopsies on Upsher's clinical patients, who had long-since exited the trial progra . Levy's later testimony revealed that he was not an expert in cholesterol-reducing drugs, and admitted that he "probably overstated" his opinion. The Commission's opinion emphasizes that it did not rely on Dr. Levy's testimony, yet again it arrives at the same conclusion, despite what we would presume to be a similar lack of knowledge in cholesterol-reducing drugs. It puzzles us that the Commission's opinion carefully traces Schering's due diligence and goes to great pains to highlight the intricate details, but still scolds Schering for not doing more.

[21] The Commission's opinion cited no authority for this assumption, but it also rejects "any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table."

[22] This opinion was offered by a Kos official, who saw the U.S. market as "more appealing than the European market." Evidence shows, and even the FTC's experts agreed, that the worldwide market Schering had acquired rights to was at least as large as the U.S. market.

discontinue its Niacor efforts in light of the poor sales effected by Kos' Niaspan.[23]

To borrow from the Commission's own words, we think its conclusion that Niacor was not worth $60 million, and that settlement payment was to keep Upsher off the market is "not supported by law or logic." Substantial evidence requires a review of the entire record at trial, and that most certainly includes the ALJ's credibility determinations and the overwhelming evidence that contradicts the Commission's conclusion. Universal Camera, 340 U.S. at 487-488, 496 (1951); see also Equifax Inc. v. FTC, 678 F.2d 1047, 1052 (11th Cir. 1982).

The ALJ made credibility findings based upon his observations of the witnesses' demeanor and the testimony given at trial. The Commission rejected these findings, and instead relied on information that was not even in the record. The Supreme Court has noted the importance of an examiner's determination of credibility, and explained that evidence which supports an administrative agency's fact-finding "may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the [agency's] ..." Id.[24] Additionally, the Court instructs that "[t]he findings of the examiner are to be considered along with the consistency and inherent probability of testimony." Id.

We think that this record consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was

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[23] Niaspan's sales were in fact disappointing. Market analysts predicted its 1999 sales to reach $169.3 million, and Schering's more conservative estimate calculated $101 million for the same year. In actuality, the sales were only $37.9 million.

[24] At the time of the opinion in Universal Camera, an "examiner" performed the same functions as an ALJ.

reliable. The Commission's finding that the "Upsher licenses were worth nothing to Schering" overlooks the very nature of the pharmaceutical industry where licenses are very often granted on drugs that never see the market.[25] Likewise, the essence of research and development is the need to encourage and foster new innovations, which necessarily involves exploring licensing options and selecting which products to pursue.

Finally, we note that the terms of the Schering-Upsher agreement expressly describes three payments totaling $60 million as "up-front royalty payments." The surrounding negotiations, trial testimony, and the record all evidence that both parties intended "royalty" to denote its traditional meaning: that Schering would pay Upsher for the licenses and production rights of Upsher's products. See e.g., Sierra Club, Inc. v. C.I.R., 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that " 'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing Black's Law Dictionary 1330-31 (6th ed. 1979)). There is nothing to refute that these payments are a fair price for Niacor and the other Upsher products. Schering-Plough made a stand-alone determination that it was getting as much in return from these products as it was paying, and just because the agreement also includes Upsher's entry date into the potassium chloride supplement market, one cannot infer that the payments were solely for the delay rather than the licenses. See Valley Drug, 344 F.3d at 1309. Thus, the substantial and overwhelming evidence undercuts the Commission's conclusion that Schering's agreement with Upsher was illegal.

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[25] At trial, the FTC selected eight products that Schering had licensed from companies other than Upsher for comparative analysis. Five of those eight products were never marketed.

2. The ESI Settlement

The Commission separately addressed Schering's settlement with ESI. Although it purported to analyze this agreement under the same scheme as it did the Upsher settlement, there is far less development of the factual record to support the Commission's conclusion that the settlement was unreasonable. At trial, the FTC called no fact witnesses to testify about the ESI settlement, and its economic expert offered only brief testimony. The Commission's opinion itself spends little time on the ESI settlement, and begins with the recognition that the case is based on "relatively limited evidence." On the other hand, Schering produced experts who posited that Schering would have won the patent case, and that the ESI's January 1, 2004, entry date reasonably reflected the strength of Schering's case. The FTC did not rebut this testimony, but rather ignored it.

It seems the sole indiscretion committed in the context of the ESI settlement is the inclusion of monetary payments. The Commission ignored the lengthy mediation process, and insisted that the parties could have reached an alternative settlement with an earlier-entry date. We do not pretend to understand the Commission's profound concern with this settlement, but it takes particular exception to the $10 million payment, which was contingent on FDA approval of the generic product. The Commission also subtly questions the validity of the $5 million for legal costs. We might only guess that if the legal fee tallied $2 million – the arbitrary cap the Commission would allow for such settlements – it would not garner the same scrutiny.

The Commission, however, refused to consider the underlying patent litigation, and its certainty to be a bitter and prolonged process. All of the evidence of record supports the conclusion of the ALJ that this is not the case of a "naked payment" aimed to delay the entry of product that is "legally

ready and able to compete with Schering." The litigation that unfolded between Schering and ESI was fierce and impassioned. Fifteen months of mediation demonstrates the doubt of a peaceful conclusion (or a simple compromise, as the Commission would characterize it).

That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court. See Standard Oil Co. v. United States, 283 U.S. 163, 170-71 n. 5 (1931) (noting that the interchange of rights and royalties in a settlement agreement "may promote rather than restrain competition"). Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence. The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001); Foster v. Hallco Manufacturing Co., 947 F.2d 469, 477 (Fed. Cir. 1991); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). Patent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits. We find the terms of the settlement to be within the patent's exclusionary power, and "reflect a reasonable implementation" of the protections afforded by patent law. Valley Drug, 344 F.3d at 1312.

C. The Anticompetitive Effects

Our final line of inquiry turns to whether these agreements were indeed an "unfair method of competition." The FTC Act's prohibition on such agreements encompasses violations of other antitrust laws, including the Sherman Act, which prohibits agreements in restraint of trade. 15 U.S.C. § 45(a); California Dental Ass'n., 526 U.S. at 763 n. 3. In California Dental, the Supreme Court required that the anticompetitive effect cannot be hypothetical or presumed. Rather, the probe

must turn to "whether the effects actually are anticompetitive." Id. at 775 n. 12.

The restraints at issue here covered any "sustained release microencapsulated potassium chloride tablet." Such a specific clause – an "ancillary restraint" – is routine to define the parameters of the agreement and to prevent future litigation over what may or may not infringe upon the patent. See Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 224 (D.C. Cir. 1986) ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose."). Ancillary restraints are generally permitted if they are "reasonably necessary" toward the contract's objective of utility and efficiency. See Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998).

The efficiency-enhancing objectives of a patent settlement are clear, and "[p]ublic policy strongly favors settlement of disputes without litigation." Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). See also Schlegal Mfg. Co. v. U.S.M. Corp., 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation ... cannot be overstated."). In order for a condition to be ancillary, an agreement limiting competition must be secondary and collateral to an independent and legitimate transaction. Rothery Storage, 792 F.2d at 224. Naturally, the restraint imposed must relate to the ultimate objective, and cannot be so broad that some of the restraint extinguishes competition without creating efficiency. Even restraints ancillary in form can in substance be illegal if they are part of a general plan to gain monopoly control of a market. United States v. Addyston Pipe & Steel Co., 85 F. 271, 282-83 (6th Cir. 1898). Such a restraint, then, is not ancillary.

Under the Schering-Upsher agreement, the scope of the products subject to the September 1, 2001 entry date demonstrate an efficient narrowness. No other products were

delayed by the ancillary restraints contained in the agreements. The '743 patent claims a "controlled release [microencapsulated] potassium chloride tablet." The language in the Schering-Upsher agreement covers the identical reach of the '743 patent. There is no broad provision that detracts from the efficiency of settling the underlying patent litigation. Nevertheless, the Commission rejected the notion that the narrow restraints were legitimate and reasonable means of accomplishing the settlement, and refused to consider that this settlement preserved public and private resources, and that the resultant certainty ultimately led to more intense competition.

The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates. Although it claimed to apply a rule of reason analysis, which we disagree with on its own, the Commission pointedly states that it logically concluded that "quid pro quo for the payment was an agreement by the generic to defer entry date beyond the date that represents an otherwise reasonable litigation compromise." We are not sure where this "logic" derives from, particularly given our holding in Valley Drug. "It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit ... litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement." Id. at 1309.

The Commission rationalizes its decision not to consider the exclusionary power of the patent by asserting that the parties could have attained an earlier entry without the role of payments. There is simply no evidence in the record, however, that supports this conclusion. The Commission even recognized that the January 1, 2004 entry date in the ESI settlement was "non-negotiable." For its part, Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts

agreed that ancillary agreements may be the only avenue to settlement.

The proposition that the parties could have "simply compromised" on earlier entry dates is somewhat myopic, given the nature of patent litigation and the role that reverse payments play in settlements. It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then settled under this scenario, the money most probably would flow from the infringers to Schering because the generics would have put their companies at risk by making infringing sales.

By contrast, the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 251 (E.D.N.Y. 2003). Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Id. Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.

By entering into the settlement agreements, Schering realized the full potential of its infringement suit – a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future. Furthermore,

although ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. Id. Ultimately, the consideration paid to Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements.

In fact, even in the pre-Hatch-Waxman context, "implicit consideration flows from the patent holder to the alleged infringer." Id. If Schering had been able to prove damages from infringing sales, and settled before trial for a sum less than the damages, the result is a windfall to the generic manufacturers who essentially keep a portion of the profits. If this were true, then under the Commission's analysis, such a settlement would be a violation of antitrust law because the infringer reaped the benefit of the patent holder's partial surrender of damages. Like the reverse payments at issue here, "such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation." Id.

The Commission's inflexible compromise-without-payment theory neglects to understand that "[r]everse payments are a natural by-product of the Hatch-Waxman process." Id. Pure compromise ignores that patents, payments, and settlement are, in a sense, all symbiotic components that must work together in order for the larger abstract to succeed. As Judge Posner emphasized in Asahi, "[i]f any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." Asahi Glass Co., 289 F.Supp.2d at 994. We agree. If settlement negotiations fail and the patentee

prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 250-52 (E.D.N.Y.2003). A prohibition on reverse-payment settlements would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." Asahi Glass Co., 289 F.Supp.2d at 994.

There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation. See generally D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 760 (2002). Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie. Id.; see also, S. Carlson, Patent Pools and the Antitrust Dilemma, 16 Yale. J. Reg. 359, 380 (1999) (U.S. patent litigation costs $1 billion annually).

Finally, the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product. The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim. See In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121, 133 (E.D.N.Y. 2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, "cleared the field" for other ANDA filers). Similarly, Hatch-

Waxman settlements, likes the ones at issue here, which result in the patentee's purchase of a license for some of the alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation. See H. Hovenkamp, et al., Anticompetitive Settlement of Intellectual Property Disputes 87 Minn. L.Rev. at 1719, 1750-51 (2003); see also H. Hovenkamp Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999).

Despite the associated benefits of settlements – which include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of party litigants – the Commission manufactured a rule that would make almost any settlement involving a payment illegal.[26] Furthermore, the Commission's minimal allowance for $ 2 million in litigation costs is rather naive. While we agree that a settlement cannot be more anticompetitive than litigation, see Valley Drug, 344 F.3d at 1312, we must recognize "[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system." 344 F.3d at 1307.

We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the "asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." Id. at 1310. An exception cannot lie, as the Commission might think, when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements).[27] The effect is the

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[26] Directly contrary to our opinion in Valley Drug.

[27] The Schering agreements would necessarily be stronger than those in Valley Drug, where the facts demonstrated the likelihood of an invalid patent, because a valid patent could operate to exclude all infringing

same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Id. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

V. Conclusion

Valley Drug established the law in our Circuit. Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannotbe the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent. Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law. Therefore, this Court grants the petition for review. Accordingly, we SET ASIDE the decision of the Federal Trade Commission and VACATE its cease and desist order.

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products for the life of the patent.

APPENDIX B

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:
TIMOTHY J. MURIS, CHAIRMAN
MOZELLE W. THOMPSON
ORSON SWINDLE
THOMAS B. LEARY
PAMELA JONES HARBOUR

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,
A CORPORATION,

UPSHER-SMITH LABORATORIES, INC.,
A CORPORATION,

AND

AMERICAN HOME PRODUCTS CORPORATION,
A CORPORATION.

Docket No. 9297

FINAL ORDER

The Commission has heard this matter on the appeal of Counsel Supporting the Complaint from the Initial Decision

and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to reverse and vacate the Initial Decision and enter the following order. Accordingly,

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Respondent Schering" means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Respondent Upsher" means Upsher-Smith Laboratories, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Upsher-Smith, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "180-day Exclusivity Period" means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(B)(iv) (2003)).

E. "AB-rated Generic Version" means an ANDA found by the Food and Drug Administration to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B) (2003).

F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2003), or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2003).

G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

H. "ANDA Filer" means a party who has filed an ANDA with the FDA.

I. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

J. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

K. "Effective Date" means the date of entering into the Agreement.

L. "FDA" means the United States Food and Drug Administration.

M. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b).

N. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

O. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

P. "Patent Infringement Claim" means any allegation made to an ANDA Filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA Product may infringe any patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.

Q. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

R. "Reference Drug Product" means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

S. "Relinquish" means abandon, waive, or relinquish.

T. "Sale of Drug Products" means the sale of Drug Products in or affecting commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44 (2003).

II.

IT IS FURTHER ORDERED that in connection with the Sale of Drug Products, each Respondent shall cease and desist, directly or indirectly, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

A. an ANDA Filer receives anything of value; and

B. the ANDA Filer agrees not to research, develop, manufacture, market, or sell the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit a resolution or settlement of a Patent Infringement Claim in which:

(1) a Respondent is either the NDA Holder or the ANDA Filer;

(2) the value paid by the NDA Holder to the ANDA Filer as a part of the resolution or settlement of the Patent Infringement Claim includes no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to

resolve the Patent Infringement Claim or $2 million; and

(3) Respondent has notified the Commission, as described in Paragraph V.

III.

IT IS FURTHER ORDERED that, when a Respondent makes or is subject to a Patent Infringement Claim in which such Respondent is either the NDA Holder or the ANDA Filer, Respondent shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. could be approved for sale by the FDA pursuant to an ANDA; and

B. is neither the subject of any written claim or allegation of Patent Infringement nor supported by a good faith opinion of counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement lawsuit in which it is either the NDA Holder or the alleged infringer ANDA Filer, such Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

A. the parties do not agree to dismiss the litigation;

B. the NDA Holder provides anything of value to the alleged infringer; and

C. the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) together with the stipulation for a preliminary injunction Respondent provides the court with the proposed Agreement, as well as a copy of the Commission's Complaint and Order in this matter;

(2) Respondent has notified the Commission, as described in Paragraph V, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) (a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission determines, at the request of Respondent, that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

PROVIDED FURTHER THAT nothing in Paragraph IV shall be interpreted to prohibit or restrict the right of Respondent unilaterally to seek relief from the court (including, but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)).

V.

IT IS FURTHER ORDERED that:

A. Each Respondent shall notify the Commission, as required by Paragraphs II and IV, in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement (hereinafter, the "First Waiting Period") and containing the following information:

(1) the docket number and caption name of this Order;

(2) a statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) identification of the parties involved in the proposed Agreement;

(4) identification of all Drug Products involved in the proposed Agreement;

(5) identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) a copy of the proposed Agreement;

(7) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the proposed Agreement.

B. If the Notification Letter is provided pursuant to:

(1) Paragraph II, representatives of the Commission may make a written request for additional information or documentary material (as if the request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material.

(2) Paragraph IV, Respondent may execute the proposed Agreement upon expiration of the First Waiting Period.

A Respondent may request early termination of the First Waiting Periods in this Paragraph V from the Director of the Commission's Bureau of Competition.

VI.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent intends to comply, is complying, and has complied with this Order. Each Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession or under their control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondents, who may have counsel present regarding such compliance issues.

IX.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which it becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: December 8, 2003

Public Record Version

In the Matter of Schering-Plough Corporation, et al.
Docket No. 9297

Opinion of the Commission

By LEARY, Commissioner:

I. Introduction and Statement of Issues

This challenging case raises important policy issues at the intersection of patent law and antitrust law. It involves the settlement of patent litigation between the manufacturer of a patented drug and two would-be generic competitors, in the context of the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), 21 U.S.C. § 355 (2001). This statute, passed in 1984, was intended to facilitate earlier entry by the manufacturers of generic drugs (the "generic"), and thereby reduce average prices paid by consumers. At the same time, Congress wanted to preserve incentives for continued innovation by research-based pharmaceutical companies (the "pioneer").[1]

The legislative compromise modified the risks and incentives in patent litigation for both pioneer and generic manufacturers. Among other things, the compromise made it possible for a generic to challenge a pioneer's patent before the generic actually enters the market, with significantly less exposure to risk of a large damage verdict if the patent is successfully defended. On the other hand, the pioneer can get an automatic stay of up to 30 months – in effect a "preliminary

[1] H.R. Rep No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48.

injunction" – without meeting the burden of proof required in a customary patent challenge.

The predictable result has been an increase in pioneer/generic patent litigation and an increase in litigation settlements. The Commission has studied litigation under Hatch-Waxman in some depth,[2] and has challenged other settlements as anticompetitive.[3] A common theme of these challenges has been that particular settlement terms delayed generic entry that otherwise would have been likely to occur. The other cases were resolved by consent orders, however, and this is the first time the Commission has addressed pioneer/generic patent settlements with the benefit of a full administrative trial and record. Notwithstanding the novelty of some issues, we have been able to examine and analyze that record under established antitrust and economic principles.[4]

The Initial Decision dismissed the complaint. After a de novo factual and legal review, we reverse and enter an order.

A. The Complaint

The Commission complaint, issued on March 30, 2001, charged that Respondents Schering-Plough Corporation ("Schering"), Upsher-Smith Laboratories, Inc. ("Upsher") and

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[2] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[3] Abbott Labs., Dkt. No. C-3945 (May 22, 2000) (consent order), complaint available at <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; Geneva Pharm., Inc., Dkt. No. C-3946 (May 22, 2000) (consent order), complaint available at <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; Hoechst Marion Roussel, Inc., Dkt. No. 9293 (May 8, 2001) (consent order), complaint available at <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[4] In addition, as discussed below, we have had the benefit of a number of judicial opinions that specifically address settlements of patent litigation under Hatch-Waxman processes.

American Home Products Corporation ("AHP") violated Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45, by entering into agreements to delay the entry of low-cost generic competition to Schering's prescription drug K-Dur 20.[5]

1. The Agreement Between Schering and Upsher

Schering sells two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10,[6] which are used to treat patients with low potassium or hypokalemia.

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[5] This opinion uses the following abbreviations for citations:

Comp. - Complaint
ID - Initial Decision of the Administrative Law Judge
IDF - Numbered Findings of Fact in the Initial Decision
CX - Complaint Counsel Exhibit
SPX - Schering-Plough Exhibit
USX - Upsher-Smith Exhibit
JX - Joint Exhibit
Tr. - Transcript of Testimony before the Administrative Law Judge
IH - Transcript of Investigational Hearing
Dep. - Transcript of Deposition
App. Br. - Appeal Brief of Counsel Supporting the Complaint
Schering Ans. Br. - Schering-Plough Answering Brief
Upsher Ans. Br. - Upsher-Smith Answering Brief
Rep. Br. - Reply Brief of Counsel Supporting the Complaint
O.A. - Transcript of Oral Argument on Appeal

References to investigational hearing or deposition transcripts included in the trial record as exhibits are made using the exhibit number with the witness's name and type of interview provided in parentheses (CX 1511 (Kapur dep.)).

The Appendix to this opinion identifies the witnesses and other people referenced in the opinion.

[6] The number in the product names refers to dosage strengths: the "20" tablets contain twice as much potassium as the "10" tablets. Russo, Tr. 3415.

Both products are covered by a formulation patent, which expires on September 5, 2006. In August 1995, under procedures established by the Hatch-Waxman Act, Upsher filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") to market Klor Con M20, a generic version of Schering's K-Dur 20. This abbreviated procedure allows a generic manufacturer to avoid the duplication of expensive safety and effectiveness studies, so long as it proves that its drug is bioequivalent to the pioneer manufacturer's already approved drug product. As part of this application, however, the generic must provide certain assurances about patents that claim the referenced drug or a method of using it. Upsher certified that Schering's patent was either invalid or not infringed by the Upsher product, a so-called "Paragraph IV" certification. Upsher subsequently notified Schering of this application and certification, as required by the Act.[7]

Schering then sued Upsher for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995. Under Hatch-Waxman, this lawsuit triggered an automatic waiting period of up to 30 months for final FDA approval of Upsher's product. On June 17, 1997, on the eve of trial, Schering and Upsher settled their patent litigation. The automatic 30-month stay was still in effect but would expire in a year, at the latest. In this settlement agreement, Schering agreed to make payments totaling $60 million to Upsher and Upsher agreed not to enter the market with any generic version of Schering's K-Dur 20 before September 2001, over four years later. As part of the settlement agreement, Upsher also licensed Schering to market six Upsher products in prescribed territories.[8] Among other

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[7] These procedures are spelled out in 21 U.S.C. § 355(j). The significance of the Hatch-Waxman Act in the antitrust analysis will be discussed below.

[8] The products are Niacor-SR, Klor Con 8, Klor Con 10, Klor Con M20, Prevalite, and Pentoxifylline. CX 348.

things, the complaint asserts that Schering's $60 million payment was unrelated to the value of these Upsher products, but rather was an inducement for Upsher's agreement to defer generic entry.

The complaint charges that Schering and Upsher violated Section 5 of the FTC Act by agreeing that Upsher would "not compete by marketing any generic version of Schering's K-Dur 20 until September 2001." Comp. ¶ 68. It states that this agreement "unreasonably restrains commerce," and thus invokes the standards of Section 1 of the Sherman Act. Comp. ¶¶ 68, 69. The complaint further invokes the standards of Section 2 of the Sherman Act, by charging that Schering "engaged in conduct intended to unlawfully preserve . . . [its] monopoly power" and that it "conspired . . . [to] monopolize." Comp. ¶¶ 70, 71.

In its prosecution of this case, Complaint Counsel argued that the settlement amounted to a horizontal agreement between the pioneer competitor (Schering) and a potential generic competitor (Upsher) that the potential competitor would defer entry, in return for the payment of money by the pioneer to the generic (sometimes referred to as a "reverse payment"[9]). Counsel claimed that this conduct was either per se illegal or subject to condemnation in a truncated proceeding.

2. The Agreement Between Schering and American Home Products

In December 1995, ESI Lederle Inc. ("ESI"), a division of American Home Products Corporation, also submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20, with its own Paragraph IV certification. Schering

[9] The payment is characterized as "reverse" because it flows from the pioneer to the generic, unlike the more common provisions of a patent litigation settlement where the alleged infringer pays royalties to the patent holder in exchange for a license.

sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996. This case was settled in principle by AHP and Schering in January 1998 and the final agreements were concluded in June of that year. As part of this settlement, AHP agreed that it would not market any generic version of Schering's K-Dur 20 before January 2004, and Schering agreed to make payments totaling $30 million. Schering also licensed two products from AHP.[10]

The complaint's characterization of the Schering/AHP agreements parallels its characterization of the Schering/Upsher agreement. The complaint states that the Schering payments were not related to the value of the licenses, and thus induced AHP to agree to the delay of its own generic product.

As noted above, AHP was named as a respondent when the Commission issued the complaint in this matter. Before the Commission's case came to trial, however, AHP agreed to a settlement, and the Commission approved a final consent order with AHP in April 2002. The legality of the agreement between Schering and AHP remains in issue, however, with respect to Schering.

B. The Defenses

Both Schering and Upsher denied that their settlement agreement was unlawful and argued additional defenses, which may be summarized as follows.

First, Respondents state there is no proof that the settlement agreement delayed the entry of generic competition for K-Dur 20. Schering's patent, which must be presumed to be valid, did not expire until September 2006, five years after the agreed-upon entry date. They argue that there is no way to know whether generic entry would have been possible at an earlier

[10] The products are enalapril and buspirone. CX 480.

date in the absence of proof on the merits of the patent litigation.

Second, Respondents state that any assumed agreement on entry was ancillary to a legitimate, procompetitive objective, namely, the settlement of patent litigation. This settlement preserved public and private resources, and the resultant certainty ultimately led to more intense competition.

Third, Respondents state that the $60 million payment to Upsher was not a payment for delayed entry but rather reasonable compensation for the side agreement involving the six products that Upsher licensed to Schering.

Respondent Schering similarly denies that the AHP agreement was unlawful and relies on the same defenses related to patent validity and the procompetitive benefits of a litigation settlement. Schering also asserts that the agreement was crafted in response to intense judicial pressures for settlement.

C. The Initial Decision

On June 26, 2002, after a two-month trial, the Administrative Law Judge dismissed the complaint in an Initial Decision that contains 121 pages and 431 numbered findings of fact. We disagree with many of the factual and legal conclusions in the Initial Decision. Notwithstanding the complexity of this matter, it is possible to identify two fundamental legal errors in the Initial Decision that led ultimately to an erroneous conclusion.

First, the Initial Decision asserted that Schering's patent gave it the legal right to exclude a generic competitor from the market, absent proof that the patent was not valid or that the generic products did not infringe. Since Complaint Counsel did not prove either invalidity or non-infringement, the Initial Decision assumed it was not possible to conclude that the settlement agreements in issue delayed generic entry that would

otherwise have occurred. ID at 4, 103-05. This conclusion is incorrect.

The Respondents did not dispute that there were separate agreements between the pioneer, Schering, and two generic competitors, Upsher and AHP, to settle two patent cases. It is also not disputed that these agreements included provisions that provided for unconditional payments from the pioneer to the two generics and also specified the time of generic entry. The issue is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments. We explain below why this question can be answered without an inquiry into the merits of the patent litigation.

Second, the Initial Decision assumed that Complaint Counsel had to prove a "relevant product market," under a traditional full-blown rule-of-reason analysis. The Initial Decision rejected Complaint Counsel's argument that market definition is not necessary when direct evidence of anticompetitive effects can be shown. ID at 4, 84-85. This ruling is also incorrect.

We follow the Supreme Court's guidance, as expressed in the California Dental case,[11] and explained at length in the Commission's recent PolyGram Holding opinion.[12] The appropriate antitrust analysis extends over a continuum, ranging from per se condemnation of particularly egregious conduct to a detailed examination of more ambiguous behavior, responsive to the facts of individual cases. Here, we will need to undertake a more detailed examination of market effects than was required either in California Dental or in PolyGram Holding, but the guiding principles are the same. We review

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[11] California Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

[12] PolyGram Holding, Inc., 5 Trade Reg. Rep. (CCH) ¶ 15,453 at 22,453-58 (FTC 2003), available at <http://www.ftc.gov/os/2003/07/polygramopinion.pdf>, slip op. at 13-29.

the agreements in this case under the rule-of-reason standard, but apply a different methodology from that set out in the Initial Decision. We conclude that the Initial Decision's approach – which defines a relevant market, calculates shares, and then draws inferences from these shares and from other industry characteristics – is not the most appropriate way to proceed in cases like this one where more direct evidence of competitive effects is available.

Once Complaint Counsel have demonstrated anticompetitive effects under the standard we apply, Respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible.[13] Because the Initial Decision concluded that Complaint Counsel had not satisfied their initial burden, it did not separately evaluate Respondents' affirmative justifications outlined in Part I.B. above. We do so.

In addition to these fundamental legal errors, we disagree with the Initial Decision's factual conclusion that the licenses granted to Schering were adequate consideration for the payments made by Schering, and that therefore the payments were not for delay. ID at 107-12. Our review of the record compels a contrary conclusion.

The Commission may review de novo both the factual findings and the legal conclusions of the Administrative Law Judge. 16 C.F.R. § 3.54(a). This de novo review includes findings on the credibility of witnesses.[14] On the basis of the totality of the record evidence, we have made de novo findings of fact that differ substantially from those in the Initial Decision. We identify these factual findings specifically and

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[13] See id., 5 Trade Reg. Rep. at 22,458-59, slip op. at 31-32.

[14] Horizon Corp., 97 F.T.C. 464, 857 n.77 (1981). This general rule is subject to the caveat that an administrative law judge has the opportunity to observe the witnesses in a live setting, but no findings of the Initial Decision in this case were based specifically on the demeanor of a witness on the stand.

discuss their significance throughout the opinion. We do, however, adopt other findings of fact in the Initial Decision, to the extent they are consistent with this opinion, most specifically those relating to jurisdiction (IDF 1-12) and certain facts about the Schering/AHP agreement (IDF 370-75).

D. Summary and Conclusions

Part II of this opinion discusses the sufficiency of Complaint Counsel's affirmative case. It will set forth in more detail the fundamental elements of the rule-of-reason methodology that we have applied and show that this methodology is consistent with existing authority. We examine the record evidence relating to both the predicted and the actual effects of the entry of generic competition for Schering's K-Dur 20 product, and we make our own factual findings. We find that Complaint Counsel have met their initial affirmative burden.

Part II of the opinion also addresses the Initial Decision's conclusion that it is not possible to determine whether the Schering/Upsher and the Schering/AHP settlements delayed entry unless we first decide the merits of the underlying patent disputes. We find that this requirement is not supported by law or by logic.

In Part III of the opinion, we address Respondent's affirmative defense that the agreement between Schering and Upsher was ancillary to the legitimate settlement of a patent dispute. We recognize that litigation settlements can conserve public and private resources and create other efficiencies. This does not mean, however, that all settlements are procompetitive, and we find that there is insufficient evidence to support the defense in this case.

In Part IV of the opinion, we address at length the claims that Schering paid Upsher $60 million for licenses rather than for delay. Our conclusion – based on the cumulative impact of

numerous documents, conversations and events – is that there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry, and that this payment substantially exceeded Schering's reasonable expectation of the value of the Upsher licenses. The details of this particular case-specific issue may not be of the same general interest as other matters discussed in Parts II and III of the Opinion, and we therefore discuss these other matters before we consider the facts on the valuation of the licenses.

In Part V, we separately discuss the particular facts and legal analysis of the Schering/AHP agreement. There is far less record evidence on this agreement but we apply the same methods of analysis and reach the same conclusions as we have done earlier with respect to the Schering/Upsher agreement. In Part VI, we explain why it is not necessary or appropriate to address the monopolization counts. In Part VII we explain why we need not rule on certain evidentiary matters.

In conclusion, after a de novo review of the record, we reject many of the findings of fact in the Initial Decision and substitute our own findings, and we further reverse the ultimate decision to dismiss the complaint. We find that both the Schering/Upsher and the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. We conclude that there is sufficient proof of adverse competitive effects; that it is not necessary to inquire into the merits of the underlying patent disputes; that the parties have not proved their ancillarity defenses; and that the payments from the pioneer to the generics were, in whole or in substantial part, consideration for delay rather than for products licensed from the generic.

Accordingly, we reverse the Initial Decision and enter an appropriate order, which is discussed in Part VIII. We note here that the order does not prohibit all settlement agreements that specify a generic entry date coupled with the payment of "value" to the generic, but excepts payments that are limited to

litigation costs up to $2 million if the Commission has been notified of the settlement.

II. The Sufficiency of Complaint Counsel's Affirmative Proof

A. Complaint Counsel's Initial Burden

The essence of Complaint Counsel's claim is that Schering agreed to pay Upsher some part of $60 million in return for Upsher's agreement to defer the launch of its generic product.[15] It is undisputed that there was an agreement that specified a future entry date and that money was paid. There is, however, a dispute over the competitive impact of the agreement and the appropriate legal standard to apply when resolving that issue.

The Commission recognized in PolyGram Holding that once an "agreement" has been proved, the prosecutor's initial burden varies according to the individual facts of the case.[16] We do not focus on labels but on the question of which party has the burden of producing what kind of evidence and when.[17] PolyGram Holding involved conduct that we called "inherently suspect."[18] In that kind of case, the focus is on the nature of the restraint, and the likelihood of competitive harm is readily apparent or can "easily be ascertained."[19] A prosecutor's initial burden can be satisfied by showing that anticompetitive effects

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[15] Similar claims with respect to Schering's settlement with AHP will be discussed separately in Part V.

[16] PolyGram Holding, Inc., 5 Trade Reg. Rep. at 22,466 n.66, slip op. at 49 n.66.

[17] A preoccupation with labels can lead, at the extreme, to an essentially meaningless distinction between per se analysis and rule-of-reason analysis that is completed in "the twinkling of an eye." Phillip E. Areeda & Herbert Hovenkamp, 7 Antitrust Law ¶ 1508a, at 391 (2003). We believe that the structure, outlined here and in our PolyGram Holding opinion, reflects a growing recognition of the limitations of semantics.

[18] PolyGram Holding, Inc., 5 Trade Reg. Rep. at 22,456, slip op. at 22-23.

[19] California Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

are likely, on the basis of "past judicial experience and current economic learning."[20]

In cases like this one, where the conduct is not inherently suspect, the prosecutor has the burden of demonstrating actual or likely market effects by reference to facts specific to the case. However, proof of these effects does not necessarily mandate the approach followed in the Initial Decision – namely, an effort to define the "relevant market" coupled with an effort to balance an undifferentiated set of factors like those listed in Brown Shoe v. United States.[21] As will appear in the detailed discussion of the evidence that follows, more direct methods are available and are preferable.[22]

In this case, Complaint Counsel made an alternative argument that the settlement agreements in issue should be characterized as either per se illegal or presumptively anticompetitive.[23] Translated into the terms of the structure outlined above, their claim was that the nature of the restraint is sufficiently troublesome to obviate specific proof of market effects.

There is some logical and legal support for this proposition. The essence of the complaint is that the pioneer paid the generics not to compete for a period of time, which could be per se illegal in other contexts. Absent a legitimate business

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[20] PolyGram Holding, Inc., 5 Trade Reg. Rep. at 22,459-60, slip op. at 29.

[21] Brown Shoe Co. v. United States, 370 U.S. 294, 321-22 (1962).

[22] The distinction between indirect and direct proof of market effects is not related to the sheer quantity of evidence that a prosecutor needs to introduce. Direct proof of competitive effects, on which we rely in this case, is not the same as a truncated analysis that would be appropriate in those cases where the nature of the restraint dominates. Direct proof is not necessarily a shortcut method; it is rather a method that relies on the most probative available evidence.

[23] App. Br. at 40, 70.

justification.[24] "naked agreements between competitors to allocate business by customers or geographic areas are routinely condemned out of hand. See, e.g., Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990); Timken Roller Bearing Co. v. United States, 341 U.S. 593 (1951). We believe that a naked agreement to pay a potential competitor to delay its entry date could logically be treated the same way because an allocation of time is analogous to an allocation of geographic space. The effects of horizontal agreements to allocate business are well understood, and it is not imperative for the Commission or a court to have firsthand experience with the practice in a specific industry context.[25]

There is also recent authority in the same industry to support a claim of per se illegality. In the Cardizem CD Antitrust Litigation, 332 F.3d 896, 908 (6th Cir. 2003), the court found that it was per se illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry. The current trend of authority seems to be moving in another direction, however.[26] The even

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[24] As articulated in the recent PolyGram Holding opinion, a legitimate business justification must be both plausible and cognizable. 5 Trade Reg. Rep. at 22,459, slip op. at 30-32.

[25] Cf. Arizona v. Maricopa County Med. Soc., 457 U.S. 332, 350-51 (1982) (per se rule does not have to "be rejustified for every industry that has not been subject to significant antitrust litigation").

[26] The Cardizem case also can be distinguished on its facts. In Cardizem, there were additional potentially anticompetitive commitments by the generic that are not present here. Unlike the present case, Cardizem involved an interim rather than a final settlement, so it would be more difficult to claim that the agreement was ancillary to an efficient disposition of the litigation. The opinion did not need to consider a claim that the generic was paid by the pioneer for licenses rather than for delayed entry. We also do not believe the opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach. See, e.g., California Dental Ass'n v. FTC, 526 U.S. 756 (1999); National Collegiate Athletic Ass'n v. Board of Regents ofthe University of Oklahoma, 468 U.S. 85 (1984).

more recent decisions in Valley Drug Co. v. Geneva Pharmaceuticals Inc., 344 F.3d 1294 (11th Cir. 2003) (reversing the district court), and in the Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), expressly considered contrary authority and declined to apply the per se label. See also In re Tamoxifen Citrate Antitrust Litig., 262 F. Supp. 2d 17 (E.D.N.Y. 2003).

In addition to the crosscurrents in the case law, we recognize – as discussed further below – that agreements of the kind challenged here can be procompetitive in limited circumstances. For example, a settlement that includes payments to a cash-starved generic might, in some circumstances, permit earlier entry than would otherwise occur. We do not believe that special circumstances of this kind have been established here, but the fact that such efficiencies are theoretically possible makes us reluctant to deal summarily with the agreements at issue in this case. See California Dental Ass'n v. FTC, 526 U.S. at 777-78.

We note that these and other potential efficiencies are also cited in support of an argument that the challenged agreements are ancillary to the settlement of litigation – an outcome that is claimed to be efficient and procompetitive overall. It is, of course, appropriate to consider an ancillarity claim, even if a particular contract term would be condemned summarily if it stood alone;[27] therefore, the mere existence of an ancillarity claim does not determine the form of analysis that should be applied. However, Respondents' claim here is that the challenged agreements were ancillary to the settlement of patent litigation. The fact that "one of the parties owned a

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[27] See, e.g., Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210 (D.C. Cir. 1986), cert. denied, 479 U.S. 1033 (1987); United States Dep't of Justice and Federal Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors, § 3.2 (2000), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,161, available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

patent . . . [which] grants its owner the lawful right to exclude others" was a complicating factor which induced the Valley Drug court to reject a per se standard. Valley Drug, 344 F.3d at 1304-06.[28] The existence of claimed patent rights was also a dispositive fact for the Administrative Law Judge in this case. ID at 4, 103-04.

We believe that it is necessary to recognize that patent issues exist as we address Complaint Counsel's initial burden of proof, and the issues cannot be resolved in a summary way – at least, not in this case of first impression for the Commission. Instead, we need to explain the reasons why the merits of the underlying patent claims are not dispositive. We also need to address the particular competitive significance of generic substitutes for patented drugs, as evidenced by economic studies, by the expectations of firms in the market, and by actual market events.

In this case, we will apply and build on fundamental principles that were discussed at length in PolyGram Holding – a Commission opinion that was itself based on a synthesis of recent Supreme Court decisions. Our PolyGram Holding opinion explains that bright-line distinctions are normally not particularly helpful; the appropriate methods of analysis extend over a continuum. This case differs from PolyGram Holding, however, not because the principles are different, but because it occupies a different place along the continuum. While a "scrutiny of the restraint itself" was sufficient in PolyGram Holding,[29] the facts of this case require us to look beyond the

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[28] See also Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 249 ("[T]he exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal.").

[29] 5 Trade Reg. Rep. at 22,458, slip op. at 29. We leave open the question whether it would be appropriate to apply this test in a future case that involved a patent settlement with payments from the pioneer to the generic manufacturer that appear to be substantially larger than reasonably anticipated costs of litigation.

nature of the challenged restraint and consider the nature of the market. As noted above, this market inquiry differs from the inquiry outlined in the Initial Decision.

B. The Evidence in Support of Complaint Counsel's Case

Complaint Counsel's affirmative case was based on an economic model, buttressed by contemporaneous records. The lead witness was an economic expert, Professor Timothy F. Bresnahan, who relied on the following three-prong test to determine whether the Schering patent settlements were anticompetitive.

> First: Did Schering have "monopoly power" in the market for K-Dur 20?
> Second: Were generics a threat to this monopoly power?
> Third: Did Schering make a payment to defer generic entry?

Bresnahan, Tr. 418-19.

Although we rely on Professor Bresnahan's testimony in part, we do not adopt his terminology. We are here concerned with whether a particular agreement was, in the language of the Sherman Act, a prohibited "restraint of trade." See Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co., 472 U.S. 284, 289 (1985). It is obviously necessary to identify the "trade" that arguably has been unreasonably restrained, but this identification is not the same thing as defining a legal "market" that can be "monopolized."[30] As explained in more detail below, it is not necessary to rely on indirect proof that

[30] The Initial Decision fails to appreciate this distinction, when it says that "Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected." ID at 85-86. The products affected by the challenged conduct were clearly identified.

Schering has a monopoly share in a relevant market when the competitive effects of the "restraint" can be shown directly.[31] Moreover, in the circumstances of this case, the first two prongs of the Bresnahan test really depend on the same evidence, because the particular significance of generic entry is what actually defines the appropriate area of trade to consider. This particular significance drives the Hatch-Waxman regulatory scheme, and is recognized in the Respondents' internal documents and in the arguments of their counsel. Conversely, the third prong of the Bresnahan test really involves consideration of two separate issues, namely, (i) the rationale for focusing on whether there was a payment by Schering, and (ii) whether Schering, in fact, paid money for deferred entry. Resolution of this latter issue requires detailed factual discussion, contained in Part IV of this opinion.

1. The Competitive Effects of Generic Entry

Most cases that are not resolved by a summary analysis begin with the definition of a "relevant market," under various tests sanctioned by case law or by agency guidelines, followed by the calculation of the sales shares of various players and concentration ratios, and conclude with an evaluation of various industry-specific factors. See, e.g., Brown Shoe Co. v. United States, 370 U.S. 325 (1962); FTC v. H.J. Heinz Co., 246 F.3d 708 (D.C. Cir. 2001); U.S. Dep't of Justice & Federal Trade Comm'n, Horizontal Merger Guidelines (1992), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,104 ("Horizontal Merger Guidelines"). In this case, the Administrative Law Judge found that Complaint Counsel had not proved their case in the traditional way, and viewed this failure as a fatal flaw. ID at 84-95. We disagree, and hold that the Initial Decision misstates

[31] See FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 460 (1986).

the requirements for proof of a violation when a summary analysis is inappropriate.[32]

There are a variety of ways to analyze market impact under the rule of reason. In FTC v. Indiana Fed'n of Dentists, 476 U.S. at 460-61, the Supreme Court said that "the finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis." A number of lower court decisions have followed this principle. See, e.g., Todd v. Exxon Corp., 275 F.3d 191, 206 (2d Cir. 2001) (evidence of "an actual adverse effect on competition . . . arguably is more direct evidence of market power than calculations of elusive market share figures"); Toys "R" Us v. FTC, 221 F.3d 928, 937 (7th Cir. 2000) (market power can be proved "through direct evidence of anticompetitive effects"); United States v. Baker Hughes Inc., 908 F.2d 981, 992 (D.C. Cir. 1990) ("'[m]arket share is just a way of estimating market power, which is the ultimate consideration,' and . . . '[w]hen there are better ways to estimate market power, the court should use them'" (quoting Ball Mem'l Hosp. v. Mutual Hosp. Ins., 784 F.2d 1325, 1336 (7th Cir. 1986))).

The Initial Decision briefly acknowledges Complaint Counsel's reliance on Indiana Federation of Dentists for the proposition that direct proof of anticompetitive effects is sufficient. The Initial Decision concludes that no such direct effects were proven because Complaint Counsel's expert did not conduct elaborate price studies. ID at 91. However, Indiana Federation of Dentists did not say that price studies are

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[32] The error is perhaps understandable because some in the antitrust community have become so accustomed to the traditional way of proceeding that they forget that this complex market analysis provides only an indirect indication that trade has been or may be restrained. It is not necessary to weigh all of these factors if a case presents more direct evidence of actual or likely competitive effects.

necessary to prove direct anticompetitive effects. On the contrary, the Supreme Court found:

> A concerted and effective effort to withhold (or make more costly) information desired by consumers for the purpose of determining whether a particular purchase is cost justified is likely enough to disrupt the proper functioning of the price-setting mechanism of the market that it may be condemned even absent proof that it resulted in higher prices or . . . the purchase of higher priced services than would occur in its absence.

FTC v. Indiana Fed'n of Dentists, 476 U.S. at 461-62 (emphasis added). The justification for use of direct evidence in this case is even stronger than it was in Indiana Federation of Dentists because the predicate offense was not just an effort to withhold useful information, but rather an agreement to defer entry by a potential competitor.

Similarly, the Seventh Circuit did not require price studies to find anticompetitive effects in Toys "R" Us, Inc. v. FTC. The court concluded that horizontal agreements that limited the distribution of particular toys to a class of retailers had obvious price effects, but did not detail what they were:

> [I]t was clear that [Toys "R" Us's] boycott was having an effect in the market. It was remarkably successful in causing the 10 major toy manufacturers to reduce output of toys to the warehouse clubs, and that reduction in output protected TRU from having to lower its prices to meet the clubs' price levels. Price competition from conventional discounters . . . imposed no such constraint. . . . Taking steps to prevent a price collapse through coordination of action among competitors has been illegal at least since United States v. Socony-Vacuum Oil Co. Proof that this is what TRU

> was doing is sufficient proof of actual anticompetitive effects that no more elaborate market analysis was necessary.

221 F.3d at 937 (citations omitted).

The Commission itself very recently explained in the PolyGram Holding opinion that "the evaluation of horizontal restraints takes place along an analytical continuum in which a challenged practice is examined in the detail necessary to understand its competitive effect." PolyGram Holding, Inc., 5 Trade Reg. Rep. at 22,456, slip op. at 22 (emphasis added).[33] We will apply this approach as we evaluate the evidence of competitive effects that was submitted as part of Complaint Counsel's case.[34]

It is important to remember what this case is and is not about. If we were evaluating the potential effects of a merger between Schering and another manufacturer of potassium chloride supplements that are functionally interchangeable with Schering's K-Dur 20, a broad market definition encompassing all prescription oral potassium supplements, which the Administrative Law Judge adopted in this case (ID at 87, citing IDF 29-118), might well be appropriate. This hypothetical merger might have some effect on the sales or prices of K-Dur 20, and it might have a more profound effect on innovation in the therapeutic category, even though the looming threat of future generic competition could ultimately transform the market entirely. A merger that threatens competition in some

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[33] This statement is supported directly by the Supreme Court's observation in California Dental that "[w]hat is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." California Dental Ass'n, 526 U.S. at 781.

[34] As stated above, the effects of the restraint involved in PolyGram Holding did not require the same market analysis as the restraint involved in this case.

substantial respect is not necessarily benign just because more substantial threats exist.

This case, however, is precisely concerned with that more substantial threat of generic competition, and there is credible evidence in the record – largely ignored in the Initial Decision – which indicates that generic entry was a uniquely significant market event, and recognized as such by both parties. Their predictions about the likely effects of generic entry, which were consistent with historic experience of other branded drugs, are just as compelling as predictions based on market shares. Moreover, these predictions turned out to be true. We therefore analyze that evidence in some detail, and set forth our own findings of fact and legal conclusions in the immediately following paragraphs. Because we have concluded that the Initial Decision's treatment of the "market" issue is inappropriate for this case, we do not adopt the Initial Decision's voluminous factual findings on the issue.[35]

2. Findings of Fact on the Competitive Effects of Schering's Agreement With Upsher

At the time of the agreement, both Schering and Upsher expected that generic entry would have a substantial impact on Schering's sales. Upsher's Klor Con M20 would have been (and eventually was) the first "AB-rated"[36] generic substitute for K-Dur 20. Easy substitutability at the pharmacy level, combined with state substitution mandates and managed care

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[35] We do not reject the findings (IDF 25-118) because they are erroneous but because they are not relevant to our legal analysis of the challenged settlement agreement.

[36] Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. Hoffman, Tr. 2278.

incentives,[37] would have caused Schering to lose rapidly a large volume of its sales to Upsher's lower-priced generic substitute. The entry of a lower-cost generic is a direct consumer benefit, by itself, wholly apart from the impact on other potassium chloride supplements. A settlement with Upsher that provided for delayed entry of this lower-cost generic product would enable Schering to maintain its sales of, and profits from, K-Dur 20 for a considerable period of time – but at significant cost to consumers. Schering's anticipated loss of sales because of generic entry provides an indication of the magnitude of the settlement's anticompetitive effects.[38]

Schering's 1997 Operating Plan, dated November 11, 1996, clearly shows that Schering expected that generic entry would dramatically erode K-Dur sales in 1998 and 1999. K-Dur sales revenues were projected to fall by 17% in 1998 and an additional 33% in 1999 from the sales levels estimated for 1997. CX 118 at SP 2300218aa. Similarly, an internal Schering analysis in June 1997, before the settlement agreement, predicted that total K-Dur revenues would drop from $190 million in 1997 to $113 million in 2000, and to $70 million in 2001. CX 750 at SP2300307aa; see also CX 123 at SP004811 (in camera). The settlement, which deferred the threat of generic entry, significantly altered Schering's K-Dur

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[37] In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at ¶ 18. A pharmacist cannot substitute a generic that is not AB-rated for a branded drug without the physician's approval. Bresnahan, Tr. 491; Russo, Tr. 3468. In some states, pharmacists are required to substitute an AB-rated generic unless the physician directs otherwise. Bresnahan, Tr. 1178; Addanki, Tr. 5998. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93.

[38] The magnitude of the expected impact on average prices can be calculated from Respondents' own internal estimates. See discussion below.

forecasts. The 1998 Operating Plan – dated November 14, 1997, after the settlement with Upsher – shows projected increases in K-Dur sales each year through 2000.[39] CX 118 at SP2300218aa-219aa.

Upsher's predictions were similar. An April 1992 analysis predicted that its entry (assumed to occur in late 1997) would reduce K-Dur 20 revenues from $184 million in 1997 to $122 million in 1999.[40] This Upsher document predicts the effects of its entry on total 20 mEq revenues for all manufacturers, namely, a drop from $184 million in 1997 to $148.5 million in 1999 (a 19% decline), even as the total number of tablets sold was expected to increase from 560 million in 1997 to 665 million in 1999 (a 19% increase). CX 150 at USL08538.[41] A simple calculation indicates that the weighted average price per tablet was expected to decline more than 30 percent, from 33 cents to 22 cents.[42]

AHP's predictions were [redacted from public record version

redacted from public record version].

The expectations of both Respondents and AHP are consistent with the impact on brand-name pharmaceutical sales generally observed upon entry of the first generic competitor.

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[39] Sales of K-Dur 10 and K-Dur 20 are combined in these documents. K-Dur 20 accounted for 86% of total K-Dur sales during 1997. CX 62.

[40] Upsher anticipated revenues of $16 million in 1999 from sales of Klor Con M20, and expected that another generic (likely Warrick) would earn $10.5 million. CX 150 at USL08538.

[41] Also, during the negotiations with Schering, Upsher sought $60-70 million based on its calculation of Schering's lost profits due to earlier entry. Hoffman IH at 35; Hoffman, Tr. 3544; Driscoll IH at 67. AHP made a similar demand. CX 1508 at 99-100 (Hoffman IH); see also Rule, Tr. 2583-84 (addressing antitrust implications of payments based on lost profits of pioneer).

[42] Upsher expected its own Klor Con M20 and another "20" product to be priced at 50% of Schering's price per tablet and the average selling price of Schering's K-Dur 20 to fall 20% due to competition. CX 150.

Studies by the Congressional Budget Office ("CBO") and economists have explored this phenomenon,[43] and all have reached similar conclusions about the impact on sales and average prices. The CBO study,[44] for example, looked at 21 drugs that first encountered generic competition between 1991 and 1993. After one year, these drugs had lost an average of 44% of sales revenue (and 42.8% of prescriptions) from drugs dispensed through pharmacies to their generic counterparts. The CBO study also found that the retail price of the generic drugs was 25% less than that of the brand-name drugs, on average. Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry at 28 (July 1998); see also Richard G. Frank & David S. Salkever, Generic Entry and the Price of Pharmaceuticals, 6 J. Econ. & Mgmt. Strategy 75, 89 (1997) ("The substantial shift in market share from brand-name to generic producers (40%-50%) along with the significantly reduced price of generic substitutes (25%-30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen."); Henry G. Grabowski & John M. Vernon, Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act, 35 J.L. & Econ. 331, 335 (1992) (the "general pattern is that generics enter at a significant discount to the pioneering product [and] . . . the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms"; "[a]verage market price [weighted by sales of the brand and generic] declined by a little more than 10 percent

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[43] Our opinion is not predicated on these studies standing alone. We rely on Respondents' own analyses, but we note that economic literature consistently shows that generic entry lowers overall average prices significantly in this industry.

[44] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, July 1998.

per year in the first two years after generic entry"); Richard E. Caves, et al., Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry, Brookings Papers on Economic Activity: Microeconomics 1 (1991) (analysis found that the price of the first generic producer is about 40% below the pre-patent expiration branded price of the drug).

The actual decline in K-Dur sales following the September 2001 entry of Upsher's Klor Con M10 and Klor Con M20 is also consistent with the expectations of both Respondents and AHP. When Upsher entered the market, its generic product was priced at approximately 50% of the price of K-Dur 20. Rosenthal, Tr. 1559. The impact on Schering's K-Dur 20 sales was dramatic: total prescriptions fell from 1,158,000 in November 2000 to 391,000 in November 2001. Schering's lost sales of 767,000 prescriptions are almost precisely offset by the sales of 703,000 prescriptions of new generic versions of K-Dur.[45] (Prescriptions for Upsher's generic version were 639,000 and Warrick's were 64,000, up from zero the previous year.[46]) During the same period, the total prescriptions for all potassium chloride products remained roughly constant.[47] In the years prior to generic entry in 2001, the sales trends for

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[45] In its post-trial brief (Apr. 15, 2002, pp. 92-93), Upsher insists that some unspecified part of the decline in Schering's sales was due to supply problems. See also ID at 99. If this is true, the magnitude of the actual loss of sales overstates the actual harm to competition from the settlement, and an assessment of damages would require us to measure this effect. However, our purpose here is to ascertain liability rather than damages, and the decline in sales is dramatic and consistent with the expectations of the parties. CX 62-65, 1480.

[46] Warrick Pharmaceuticals Corporation is a subsidiary of Schering that produces generic pharmaceutical products. In some situations, Warrick produces generic versions of Schering's patented products when another generic version of the drug has entered the market.

[47] Total prescriptions were 2,716,000 in November 2000 and 2,758,000 in November 2001. CX 1480 at SP 089837. This pattern of sales might suggest that K-Dur 20 and its generic substitutes were actually in a relevant "market" by themselves, if it were necessary to define a market in this case.

K-Dur 20 had been similar to those for all potassium chloride products.[48] CX 62-65; see also SPX 1123 at AHP 1300115, 1300117. Schering's concerns about generic entry were obviously well founded.

3. Schering's Attempt to Discount These Competitive Effects

Schering advances two arguments in an attempt to explain away the significance of a growth in generic sales at the expense of pioneer sales. Schering argues, first, that part of the generic's sales performance is attributable to state laws that mandate the substitution of lower-priced generic drugs and the fact that payors often insist on such substitution. Schering argues, second, that the sales of its own drug are also adversely affected by the fact that it is common practice in the industry for the pioneer drug manufacturer to cut back on sales promotion efforts after a generic substitute becomes available. Schering Ans. Br. at 72-74. There is obviously a concern that sales promotion will confer a "free riding" benefit on all competitors, but these concerns apparently are magnified for a particularly close competitor like a generic. We accept that the factual predicate for these arguments may well be true, but these facts actually support Complaint Counsel's case rather than Schering's. They merely underscore the well-recognized unique impact of generic competition.

Generic pharmaceutical competition is conducted in a special legal environment that differs in significant respects from a truly unregulated market place. In addition to state generic substitution laws, competition is affected by the requirement for FDA approval and by the regulatory provisions of Hatch-Waxman. All markets are affected by regulation to

[48] Evidence of this kind might have a bearing on whether Schering was a monopolist before generic entry, but we do not reach that issue in this case. See Part VI, below.

one degree or another, however, and these regulations need to be accepted as real market factors in an antitrust analysis – not simply assumed away. If entry were an issue in a merger case, for example, it would be entirely appropriate for a decisionmaker to take into account import restrictions or environmental impediments to expansions of plant capacity.[49]

Moreover, in the case before us, the existence of state substitution laws, as well as payors that mandate substitution on their own, provides an additional argument for treating generic competition as likely to have a particularly substantial impact. The underlying premise of these laws and payor practices is that generic competition has the potential to lower prices, and therefore should be promoted.[50] The executives of Schering and Upsher who negotiated the settlement in issue must have been aware of these laws and practices, and the effects that they have had in their industry. The internal market predictions of their respective companies take entry into account. It is not unreasonable to assume that, armed with this knowledge, they expected Upsher's entry to create the precise competitive threat that actually defines the area of trade we need to focus on here.

Similarly, if drug manufacturers react to generic entry by reducing promotions, as Respondents claim, it is further evidence that generic competition by itself has a significant effect. These reactions – along with the reactions of payors and state substitution laws – are consistent with our conclusion that generic competition is the closest substitute and that there is an adverse competitive effect, even though a broad "market" might be defined for another purpose.

Upsher advances still another argument to explain why the introduction of its own generic was so successful. It claims that

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[49] See Horizontal Merger Guidelines §§ 1.43, 3.1.

[50] See Andrx Pharms. v. Biovail Corp., 256 F.3d 799, 809 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast."), quoting In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991).

the delayed entry negotiated in the settlement agreement was actually procompetitive because the company was able to increase its capacity and enter in force on a date certain, with greater market impact. Upsher Ans. Br. at 38-41. This argument appears to be inconsistent with the internal market forecasts, discussed above, which predicted substantial earlier entry. Upsher also does not explain why it needed to delay entry for over three years beyond expiration of the Hatch-Waxman stay. In fact, after the consummation of the agreement, Upsher slowed the pace of its work on the launch of Klor Con M20 and shuffled Klor Con personnel to other projects. Kralovec, Tr. 5094. Work on the launch was suspended for a time, and the new launch team was not gathered until May 1999. Kralovec, Tr. 5094; Gould, Tr. 5116, 5173. Even with this delay, Upsher considered that it was starting this work in ample time for the September 2001 launch. Kralovec, Tr. 5046-47; Gould, Tr. 5116, 5118-19. This suspension may have been a sensible business decision in the circumstances, but it undercuts any argument that a three-year delay was a requisite for substantial entry.

We therefore conclude that there is substantial evidence to support Complaint Counsel's claim that delayed generic entry in this situation would harm consumers by depriving them of the choice of a lower-cost generic version of K-Dur 20. We now discuss why we believe that Schering's payment resulted in a greater delay than would otherwise have occurred.

4. The Particular Significance of Schering's Payment

A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. In light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of

differing litigation expectations.[51] Complaint Counsel's entire case proceeds on the theory that the payment of money by Schering to a potential generic entrant is what makes this case different. As Bresnahan stated:

> [W]hat matters is the difference between the amount of competition we got here . . . versus the amount of competition that was likely to occur had it not been for the payment to delay. . . . It's that comparison that matters, not the absolute amount.

Bresnahan, Tr. 614. We agree.

If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration,[52] it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date

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[51] The Commission's study of patent settlements under the Hatch-Waxman Act identified a large number of unchallenged agreements where the parties settled on a deferred entry date. The Commission study uncovered two agreements (Drug Products G and H in Chart 3-2) in which generic entry occurred under royalty-free licenses. The large majority of agreements in which generic entry occurred prior to patent expiration involved situations in which the generic applicant paid a royalty to the brand-name company during the remaining patent life (Drug Products A-F in Chart 3-2). Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 29 (July 2002). These particular facts, based on a non-record source of which we take notice, have not been disputed by any of the parties (although Respondents did object to other data in the study). See Order Granting Motion for Leave to File Reply Memorandum; Denying Motion to Strike Reliance on FTC Study; and Permitting Each Party to File a Brief Addressing Cited Facts Contained Therein (Jan. 6, 2003).

[52] In this case, of course, Respondents have attempted (but failed) to demonstrate that there were other offsetting considerations adequate to account for the payment. See discussion in Parts III and IV, below.

that represents an otherwise reasonable litigation compromise.[53] Cf. FTC v. Indiana Fed'n of Dentists, 476 U.S. at 456 (FTC's conclusions supported by "common sense and economic theory, upon both of which the FTC may reasonably rely"); see also Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391 (2003); Herbert Hovenkamp, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1757-61 (2003).[54] The nexus between payment and delay is supported not only by simple logic but also by the plain language of the settlement agreement and the history of the negotiations between the parties. See Part IV, below.

According to Bresnahan, there is also a powerful incentive for the contending parties to make these agreements. The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete. It would be mutually beneficial for the patent holder and the challenger to defer entry of the generic and split the patent holder's profit. Bresnahan, Tr. 426-29, 495, 612-13; Goldberg, Tr. 119-20;

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[53] This is the first subsidiary issue subsumed in the third prong of Professor Bresnahan's test.

[54] We are aware of the recent opinion in Asahi Glass Co., Ltd. v. Pentech Pharms., Inc., 2003 U.S. Dist. LEXIS 19370 (N.D. Ill. 2003) (Posner, J.), which questioned whether these concerns about reverse payments are based on "a sound theory." Id. at *21. Since the comment was made in passing and was admittedly "inapplicable" to the case before the court, we only note it here. To the extent that the court was opposed to per se condemnation of reverse payments, we emphasize that we have not applied a per se standard in this case and we have acknowledged that there are possible arguments in justification. More broadly, the court seems to be concerned that prohibition of "reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options[.]" Id. Any antitrust restrictions on settlement agreements have the effect of reducing settlement options, but Judge Posner expressly states in the same opinion that some provisions should be condemned. Id. at *11-13.

Kerr, Tr. 6261. The resulting adverse effects on consumers are obvious.

We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences. Compare Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 591 n.15 (1986) (the Court recognized that weak incentives make price predation highly unlikely).

One recent district court decision expresses a different view of incentives, in a lengthy opinion that we need to address. In the Ciprofloxacin Hydrochloride case, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), one reason for the court's rejection of a per se standard was its conclusion that Hatch-Waxman settlements are "unique" because the statute has distorted the relative bargaining power of the litigating parties. Id. at 250-52. In what the court called a "traditional scenario," a party can challenge a patent only by entering the market with its infringing product and risking a lawsuit for substantial damages. Id. at 251. The court went on to say that the event that triggers litigation under Hatch-Waxman – an ANDA filing with a Paragraph IV certification – is an "artificial act of infringement." Id. This "artificial act" eliminates the generic's potential exposure to liability for the pioneer's "enormous losses," and thus deprives the pioneer of its "traditional leverage" in litigation. Id. According to the court, this shift in the relative bargaining power of the parties means that "so-called reverse payments are . . . a natural by-product" of the Hatch-Waxman process. Id. at 252.[55]

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[55] This argument is cited with apparent approval in the Valley Drug case, 344 F.3d at 1309.

We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that. However, because of the economic reality that generic entry causes a loss to the pioneer well in excess of the generic's anticipated profit, and the fact that damages for infringement are based on the pioneer's lost profit, a generic litigant still risks losses well in excess of its anticipated gains. This powerful disincentive for patent challenges may have been "traditional," but Congress specifically decided that it wanted to encourage patent challenges for pharmaceutical products. (An offsetting concession for patent holders is the automatic 30-month stay.)[56] As stated above, antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework.

A payment for delayed generic entry under a Hatch-Waxman framework is no less anticompetitive than a similar payment under the "traditional" regime. The shift in the relative bargaining power of the litigating parties may mean – assuming other factors are held constant – that pioneers will have to accept earlier entry dates in settlement than they would otherwise have had to do. The baseline for a competitively benign settlement may have shifted. Whether this is good or bad is a judgment for Congress to make. Furthermore, we do not have evidence before us to justify any conclusion that payments by pioneers to generics are a "natural by-product of the Hatch-Waxman process"[57] or that Congress intended to immunize payments of this kind.

We therefore believe that the possible existence of a so-called "reverse payment" raises a red flag that distinguishes this

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[56] H.R. Rep. No. 98-857, supra note 1, at 28, 1984 U.S.C.C.A.N. at 2661. See also Andrx Pharms. v. Biovail Corp., 256 F.3d at 802 (Congress "interested in increasing the availability of generic drugs" but also interested in protecting "the patent rights of the pioneer applicant").

[57] See also discussion of ancillarity in Part III, below.

particular litigation settlement from most other patent settlements, and mandates a further inquiry.[58] All of the pioneer/generic patent settlements that we have thus far challenged included a payment of this kind.[59] In fact, the evidence indicates that antitrust counsel for the pioneer, Schering, was also concerned about the legal implication of a possible payment to generic challengers. See, e.g., CX 1494 at 71 (Driscoll IH); CX 1509 at 35 (Hoffman IH); Rule, Tr. 2583-84. However, for the reasons discussed above and in Part III below, we are not now prepared to say that all such payments should be viewed as per se illegal or "inherently suspect." We believe that this particular case warrants a more extensive analysis of competitive effects, without foreclosing the possibility that a more truncated process would be appropriate in some future case.

C. The Need to Address the Merits of the Underlying Patent Dispute

The Respondents argued, and the Administrative Law Judge held, that proof of anticompetitive effects requires proof on the merits of the underlying patent claims. ID at 4, 103-04. We deal with the argument in this segment of the opinion because it is not really a "defense" but rather a fundamental attack on the sufficiency of Complaint Counsel's affirmative case. It is also an argument that, if valid, would have an impact not only on this particular case but also on other antitrust cases before the Commission and the courts that involve the legality of patent settlements.

Respondents' argument and the conclusions of the Initial Decision on this issue have a superficial appeal. The argument proceeds as follows: Complaint Counsel have the burden of

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[58] See supra note 51.

[59] See cases cited supra note 3.

proving that the agreement delayed generic entry but failed to prove that earlier entry would have been possible in the first place, in light of the patent blockade. By statute, Schering's patent is presumed to be valid (35 U.S.C. § 282) and Complaint Counsel failed to prove it was not. Since the holder of a valid patent has the right to exclude infringing products entirely for the life of the patent, the settlement agreement was procompetitive because it permitted generic entry some five years before the expiration of Schering's patent.

We reject this argument for a number of independent reasons. First, Schering's presumptively valid patent did not necessarily confer a right to exclude generic entry in the circumstances of this case. Second, there is a recognized distinction between the standard for proving that an agreement is likely to cause competitive harm and the standard for proving damages after the fact. Third, we believe that an inquiry into the merits of the patent case would not be conclusive in most of our antitrust cases anyway. Fourth, we are also concerned that a mandated inquiry into these issues, as part of an antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation.

We observe, first, that the Initial Decision suffers from a fundamental logical flaw. The fact that Schering may have held a presumptively valid formulation patent on K-Dur 20 does not mean that it had a presumptive right to preclude the entry of Upsher's generic product. One issue in the patent case – perhaps the most important one – was not whether Schering's patent was valid but rather whether Upsher's product infringed the patent. IDF 129, 130. On this issue, Schering had the burden of proof.[60] We cannot assume that Schering had a right

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[60] See, e.g., Carroll Touch, Inc. v. Electro Mechanical Systems, Inc., 15 F.3d 1573, 1578 (Fed. Cir. 1993). The Initial Decision assumed that Upsher had the burden of proving either patent invalidity or "that its product . . . did not infringe Schering's patent." ID at 103 (emphasis added). This is not correct.

to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

Second, we are not aware of any federal court opinions that hold it is necessary for complaint counsel in a government proceeding to offer proof on the underlying merits of the patent dispute, in order to establish their affirmative case. The point was discussed in the recent Tamoxifen Citrate Antitrust Litigation, 262 F. Supp. 2d 17, where the court dismissed an antitrust challenge to an agreement that settled a patent dispute between a pioneer and a generic manufacturer, with terms that included a payment from the pioneer to the generic. In return, the generic had agreed not to market its own version of the Tamoxifen drug prior to the expiration of the patent, but instead took a license to sell product manufactured by the pioneer.

In that case, however, the validity of the pioneer's patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, the pioneer's patent was successfully defended in litigation with three other generic challengers. In a private action for damages, after the fact, the Tamoxifen court had good reason to believe that the settlement did not ultimately cause consumer harm. In the present case, on the other hand, we do not attempt to assess damages but rather look at the agreement as of the time it was made to determine whether it was "unreasonable," i.e., whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement.

A contemporaneous opinion from the same district court in the Ciprofloxacin Hydrochloride Antitrust Litigation, discussed at length above in connection with another issue, expressly rejected the argument that an antitrust attack on a Hatch-Waxman settlement requires proof on the merits of the

underlying patent case. Notwithstanding the fact that the underlying patent dispute between the pioneer and the generic manufacturers involved patent validity, not infringement, and the fact that subsequent to the settlement the pioneer had successfully defended the validity of its patent in litigation with others, the court found that the existence of an antitrust violation does not depend on the merits of the patent case.[61] At the time of the settlement, the parties did not know who would ultimately prevail, and the court noted that

> ... the challenged agreements allowed [the generic] to accept cash in exchange for an agreement to halt the process by which a court would make ... a determination [of patent validity and infringement] – a process encouraged by the Hatch-Waxman Amendments and beneficial to consumers.

Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 204. The court therefore rejected the pioneer's argument that it was patent law, not the agreement, that precluded generic entry. Although the court also rejected plaintiffs' claim of per se illegality, it indicated that the matter could proceed under a rule-of-reason inquiry. Id. at 210-11.

We agree with the reasoning of the Ciprofloxacin Hydrochloride court on this issue. The merits of the patent litigation may be crucial in an action for damages but we are here concerned only with legal liability, and we focus on the state of the world as it was perceived by the parties at the time

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[61] The Ciprofloxacin court appropriately cautions that the standard for proof of damages may be different. Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 199.

that they entered into the settlement agreement, when they could not be sure how the litigation would turn out.[62]

A similar view was expressed by the court in Valley Drug, cited earlier for its rejection of a per se standard. In Valley Drug, the sole issue in the underlying patent litigation was patent validity and, after an interim settlement, the patent in issue had been declared invalid in a separate proceeding. The court said:

> We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to per se condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are [sic] to be judged at the time the agreements are entered into.

Valley Drug, 344 F.3d at 1306 (citations omitted).

The court went on to say:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

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[62] The uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced. If, for example, an incumbent entered into an agreement with a would-be market entrant in which the latter agreed to delay or forgo introduction of a new product, it would be no defense to argue that the new product might not have succeeded in any event.

Id. at 1308.

The Valley Drug opinion, of course, was concerned only with the narrow issue of whether a subsequent finding of patent invalidity necessarily made it per se illegal for the pioneer patent holder to pay a generic challenger for entry delay – even though the litigation outcome was uncertain at the time. We believe, however, that the underlying logic of the opinion has a broader application. We question the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case. This is the third independent basis for our conclusions.

In an extreme case, the inquiry might be helpful. If it appeared that the patent claim was objectively a sham, any agreement to delay generic entry might be viewed as anticompetitive, regardless of the other terms. Conversely, if it appeared that the generic's Paragraph IV certification was objectively a sham, it might be difficult to claim that an agreed-on entry date before the patent termination involved an unacceptable delay.[63] The problem is that the bulk of the cases will lie in between.[64]

An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be

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[63] A case like Tamoxifen (discussed above), where patent validity was the only issue and the patent had been repeatedly upheld, might also be included in this category.

[64] Take the simplest possible case as an example. Suppose it appears post settlement that each party reasonably had a 50/50 expectation of victory. Does this mean that a 50/50 split of the remaining patent term would be the only reasonable settlement? This assumption would not necessarily be true for reasons that the Respondents themselves have addressed in great detail. See Part III, below. The parties may have very different financial resources, profit expectations and risk preferences, with consequently differing views on the costs and benefits of further litigation. These differing views would have an effect on the outcome of settlement negotiations, and litigation odds cannot be converted directly into the legally acceptable period of delayed entry.

particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement. We observe this natural phenomenon in the present case. Upsher's ANDA filing had certified that Schering's K-Dur 20 patent was either invalid or not infringed by Upsher's product. Later on, Upsher's counsel in the patent litigation represented to the court that the only impediment to its immediate entry was the automatic Hatch-Waxman stay. CX 1705 at USL PLD 004242 (in camera); Kerr, Tr. 6744-45. After the settlement, Upsher's views dramatically changed. At trial, Paul Kralovec, Upsher's CFO, testified that, because of the financial risk arising from damages for infringement, a decision was made that Upsher would not market Klor Con M20 until the outcome of the litigation was known. Kralovec, Tr. 5037-38.

The fact that the generic's counsel has switched sides does not destroy all potential for an adversary proceeding. It is theoretically possible for Complaint Counsel to step in for the generic's newly complaisant counsel and champion the generic's abandoned claims, or the Commission could weigh conflicting opinions of opposing experts. If it were logically necessary to decide the issue of patent validity in order to decide whether the agreements in issue here were reasonable, we would do so – regardless of the difficulties. However, for the reasons discussed, it is not necessary.

Finally, we have considered the serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight. Under the standard we adopt here, if the parties simply compromise on the entry

date, standing alone, they do not need to worry about a later antitrust attack. This test may not be perfect, but at least it is easy to apply at the time of settlement, when the outcome of the patent case is uncertain. If a subsequent examination of the merits were decisive, the parties could not be sure. If the generic's position were later determined to be invalid, then any entry short of patent expiration would likely be immune from attack. If, however, the pioneer's position were found to be invalid, any delay would be suspect. Respondents' argument might serve their interests in this particular case, but it could have a chilling effect on patent settlements down the road, and thus make it harder for parties to enjoy the advantages of certainty.[65]

For these various reasons, we believe that it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements. To the extent that the opinion of the Administrative Law Judge is predicated on any such requirement, it is reversed.[66]

III. The Ancillarity Defense

Both Schering (implicitly) and Upsher (expressly) plead that even if the $60 million payment to Upsher were deemed to have been traded for delay, it was justified as ancillary to a legitimate, pro-consumer agreement, namely, the settlement of a patent dispute. Schering Answer at ¶¶ 1-3; Upsher Answer at Defenses ¶ 10. They offered evidence – principally through their expert witness, Professor Robert Willig – that Professor Bresnahan's paradigm was overly simplistic. Professor Willig

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[65] See Valley Drug, 344 F.3d at 1306-07; Willig, Tr. 7148, 7173-75.

[66] For reasons also discussed above, however, this conclusion about what the Commission needs to do in this case does not necessarily have any bearing on what a private plaintiff may need to do in order to prove damages.

testified that the payment of net consideration from the pioneer to the generic must be considered in the overall context of procompetitive patent settlements that it may facilitate. We, therefore, will examine these claims under familiar principles applicable to ancillarity defenses.

The Antitrust Guidelines for Collaborations Among Competitors[67] set out the analytic framework that we will apply in this situation.[68] These Guidelines (Sec. 3.2) provide that even a provision that would be per se illegal standing alone can qualify for rule-of-reason treatment in certain circumstances. Therefore, even if we assume that Schering overtly agreed to pay Upsher a substantial sum for delayed entry, it is necessary to examine that payment in the context of an overriding purpose to settle the patent case.

Under the Guidelines, respondents who assert an ancillarity claim have the burden of showing three things (Sec. 3.2):

> (i) that there is an "efficiency-enhancing integration of economic activity ...";
> (ii) that the arguably ancillary agreement is "reasonably related to the integration ..."; and
> (iii) that it is also "reasonably necessary to achieve ... [the] pro-competitive benefits" of the overall arrangement.

Id.

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[67] See Antitrust Guidelines for Collaborations Among Competitors, supra note 27.

[68] The Guidelines are intended to reflect current law, not to catalyze changes. See Susan S. DeSanti, Guideposts in the Analysis: The Federal Trade Commission and U.S. Department of Justice, Antitrust Division Competitor Collaboration Guidelines, Address Before the Houston Bar Association (Dec. 7, 1999), available at <http://www.ftc.gov/speeches/other/antitrustguidelines.htm>.

We accept Willig's testimony that there are likely to be efficiencies associated with the settlement of patent disputes between pioneer and generic manufacturers. See, e.g., Willig, Tr. 7134, et seq. A settlement can save public and private resources that would otherwise be consumed by litigation, and it can provide certainty that will encourage business investment. We also recognize, as he testified, that there may be hypothetical situations where a procompetitive settlement could require payment of some money to the generic challenger. This means that we are unwilling to say reverse payments included in a settlement agreement are always illegal.[69] On the other hand, the mere articulation of hypothetical circumstances where reverse payments could ultimately facilitate an efficiency-enhancing settlement does not mean that a particular settlement is legal. If Complaint Counsel have made out a prima facie case that the agreement was anticompetitive, the burden is on these Respondents to demonstrate that these hypothetical circumstances describe the realities of the present case. They have not done so.

Willig hypothesized, for example, that a "cash starved" generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer. Willig, Tr. 7180, 7188, 7258. It is possible that this trade might ultimately yield competitive benefits, but a respondent that relies on this argument also must show that the generic, in fact, was cash starved; explain why the pioneer was the best source for the necessary funds; and demonstrate that the up-front support actually resulted in an entry date earlier than would be expected without it. We have no evidence that

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[69] See Bristol-Myers Squibb Co., FTC Dkt. No. C-4076 (Section XII(B)(1)(b) of Decision and Order does not prohibit respondent from settling patent infringement litigation with a payment from the pioneer to generic manufacturer if payment is less than $2 million or expected litigation costs), available at <http://www.ftc.gov/os/2003/03/bristolmyersdo.pdf>. See also Final Order in this case, at Paragraph II.

would establish these conclusions. To the contrary, Upsher expressly waived any intention to rely on financial need as a defense in this action.[70] It is true that Schering may have believed Upsher needed the money because Upsher's lead negotiator said so repeatedly in the course of the settlement discussions, but it is also true that Schering did not rely on any such belief to establish the legality of the $60 million payment. See discussion in Part IV.B., below. As a matter of fact, Upsher was not cash-constrained; the company passed on to its shareholders an amount equal to or in excess of the sums received from Schering. Kralovec, Tr. 5067.

There are other possibilities. Risks and costs associated with litigation are avoided by settlement. If the generic challenger is more optimistic about the litigation outcome than the pioneer, a pioneer may be willing to pay some money to bridge the gap in the expectations. Willig, Tr. 7195; Addanki, Tr. 5761, 5776, 5793. It is also possible that there are widely differing risk preferences. A judgment-proof generic manufacturer may be willing to hold out for "unreasonable" settlement terms because its downside risks of damage exposure are small.[71] Addanki, Tr. 5793-94.

We recognize that additional legitimate justifications can also exist, and this is another reason why we do not apply a truncated analysis in this particular case. However, once Complaint Counsel have made out a prima facie case of actual

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[70] CX 1693 (Letter from Rajeev K. Malik to Yaa A. Apori Providing Upsher's Responses to Specifications 4, 5 and 8 of Complaint Counsel's First Request for Production of Documents (Aug. 28, 2001) ("The agreement is Upsher-Smith does not have to produce documents in response to Specification 8 [requesting financial information]. In exchange, Upsher-Smith commits to Complaint Counsel that it will not raise a defense that uses Upsher-Smith's financial condition as a justification for entering into the licensing agreement with Schering-Plough.")).

[71] For the reasons discussed above, it may be difficult to identify a particular settlement demand as objectively "unreasonable."

anticompetitive effects, Respondents must do more than suggest hypothetical benefits.[72]

In this case, the sheer magnitude of the payment from the pioneer to the generic is a particular source of concern. Even if we assume arguendo that there had been enough evidence to show that the hypothetical speculations of Respondents' experts actually applied to the facts of this case, the evidence could not justify a payment of any amount close to the $60 million involved here. We deal with an ancillarity defense predicated on the notion that there is a strong public policy in favor of litigation settlements – even if the settlements may involve agreements that might be illegal standing alone. But, these public policy considerations are just one weight on the scale; they do not mean that all settlements are presumptively efficient regardless of the cost.[73]

We conclude that Respondents' ancillarity defense has failed. A payment in the order of $60 million could not be defended under these facts as a reasonably necessary element of a settlement that is procompetitive overall. The parties did not show that the hypothetical situations where such a payment might be justified actually were present in this case. The ancillarity claim is rather based on after-the-fact rationalization. During the course of the settlement negotiations, recounted in detail below, Upsher's representatives seemed to be entirely oblivious to the potential legal consequences of their demand that money be paid for delayed entry. Schering's representatives were sensitive to these concerns but believed

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[72] PolyGram Holding, Inc., 5 Trade Reg. Rep. at 22,459, slip op. at 30-31 ("a justification must plausibly create or improve competition.").

[73] Herbert J. Hovenkamp, et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719 (2003) (payment by a pioneer to a generic in excess of litigation costs is not an economically efficient solution to the dispute and likely biases the negotiated entry date toward later entry).

that the solution was to find some side deal that would justify the payment by itself. We now examine Schering's "solution."

IV. Consideration for the Upsher Licenses Granted to Schering

Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher. App. Br. at 3. We interpret this to mean that Complaint Counsel's test is whether $60 million was a fair price for the licenses from Schering's standpoint, regardless of what they were worth to Upsher.[74] We express no view as to whether a concession of this kind is necessarily appropriate. Since, however, it is the basis on which this case has been litigated, we will proceed on the same premise.

This is also an issue on which Complaint Counsel have conceded that they bear the ultimate burden of proof. O.A. at 30 ("we have the burden to prove the payment was for delay"). This is not to say that Complaint Counsel bear the burden of proving the actual value of the licenses. What we understand they have undertaken to prove is (i) that there is a nexus between the payment by Schering and Upsher's agreement to delay its competitive entry, and (ii) that the preponderance of the evidence shows that this payment exceeded, by a substantial amount, Schering's reasonable expectation of the value of the Upsher licenses. App. Br. at 22-24 (" . . . the Commission need not conclude that the license for [Niacor-SR] was a 'sham' or that it lacked any value to Schering."). This is the standard that we will apply.

The Initial Decision contains extensive findings on this issue. However, for reasons that will become clear, many

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[74] Complaint Counsel's witness Bresnahan testified that "if Schering-Plough had made a stand-alone determination that it was getting as much in return from these products as it was paying, then I would infer that they were not paying for delay." Bresnahan, Tr. 964-65.

specific findings and the ultimate factual conclusions in the Initial Decision are flawed. Accordingly, we review the entire factual record de novo, and, where appropriate, substitute our own findings and conclusions for those in the Initial Decision. We will focus on (A) the plain language of the agreement; (B) the background and history of the settlement negotiations; (C) the extent of Schering's internal investigation of the value of the Upsher licenses, considered in light of the information it had already obtained in the course of recently terminated negotiations with another company for a similar product; and (D) the inferences that may appropriately be drawn from the subsequent conduct of the parties and after-the-fact opinions about the value of the licenses.

This part of the opinion is necessarily detailed. There is no single event, no single communication, that determines the outcome. Our conclusion that Complaint Counsel have sustained their burden on the critical valuation issue rather depends on the cumulative impact of the extensive record evidence in this case.

A. The Language of the Settlement Agreement

The "Detailed Agreement Terms" between Upsher and Schering provide, in pertinent part:

> 3. Upsher-Smith agrees that it will not market in the United States its KLOR CON® M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001.
>
> * * *
>
> 11. In consideration for the licenses, rights and obligations described in paragraphs 1 through

> 10 above, SP licensee [a Schering affiliate] shall make the following payments to Upsher-Smith:
>
> ...

CX 348 at USL03186, USL03188.

The contract then sets out a schedule for payment of $60 million, keyed to specific time periods following approval by the Schering Board. The payments are not dependent on milestones in the development of products licensed from Upsher to Schering, such as FDA filings or approvals.[75] The only ongoing affirmative obligation of Upsher, apart from its commitment not to enter before September 1, 2001, is a promise that it will not assist ESI or any other party that challenges Schering's patent. CX 348, Par. 6.

We do not believe this contractual language is conclusive by itself. What it does show is that at least part of the consideration for the $60 million payment was Upsher's commitment to delay entry, something that Schering's in-house counsel has readily conceded. Hoffman, Tr. 3565-67. Even more significant, payment was not conditioned on Upsher's cooperation with Schering in the development of the licensed product. The omission may well have been deliberate because, after the Agreement became effective, Upsher did practically nothing to cooperate and Schering did not seem to care. See discussion in Part IV.D., below.

B. Background and History of the Negotiations

The Initial Decision relies on direct trial testimony of several individuals for a description of the negotiations between the parties that resulted in the June 17, 1997 agreement. IDF 131-55. It does not cite contradictory cross-examination

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[75] Additional contingent milestone payments that could total $10 million were negotiated for the launch of Niacor-SR in nine other countries.

testimony or investigational hearing testimony of several of these individuals, nor does it explain why this testimony was given no weight – even when the contradictory testimony is corroborated by documentary evidence.[76] There are particularly significant discrepancies in the testimony of Ian Troup, Upsher's President and Chief Operating Officer, and John Hoffman, Schering's Associate General Counsel. Accordingly, as detailed below, the Commission discounts inconsistent trial testimony of these two individuals.

The Initial Decision also does not cite important deposition testimony of a primary negotiator for Schering in the early meetings between the two companies (Martin Driscoll, Vice President of Sales and Marketing for Key Pharmaceuticals), even when it is consistent with his investigational hearing testimony. See, e.g., CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.) (views of the parties about payments to Upsher and entry into the market). The Initial Decision relies on direct testimony of some witnesses for facts about which they had no firsthand knowledge and for which other individuals with differing testimony would have been more reliable sources. For example, IDF 136 relies on Hoffman, who did not attend either the May 28 or the June 3 meeting, for a

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[76] Upsher continues to press its objection to the use of the testimony of Schering executives during the investigational hearings and to rely on a pretrial ruling that this testimony is not admissible against Upsher. Upsher Ans. Br. at 22 n.2, citing Tr. 297-98. We do not agree with this ruling. See Gibson v. FTC, 682 F.2d 554, 568 (5th Cir. 1982) ("[T]he Commission Rules of Practice [§ 3.43(b)] permit the introduction of hearsay evidence, provided that it meets the standards of materiality, reliability and relevance."). The hearing transcripts in issue are verbatim statements of the witnesses, and Upsher does not explain why they are unreliable. In any event, however, we rely on these transcripts merely to corroborate evidence from other sources. The testimony specifically affected by this ruling is contained in CX 1483, 1494, 1508, 1510, 1515 and 1531. There is independent support for any factual findings in this Opinion that may also refer to these exhibits.

description of the events at these meetings. IDF 145 relies on Troup's recollection of a discussion with Schering personnel of certain clinical data about Niacor-SR, but these Schering employees had no knowledge of these issues.

The Initial Decision also relies on self-serving statements of the parties without weighing contradictory, and more reliable, evidence.[77] For example, IDF 145 indicates that the parties discussed "the market potential for Niacor-SR" and that they also "discussed niacin combination therapy, the advantages of Niacor-SR versus immediate-release niacin, the flushing side effects and Niacor-SR's effects on Lp(a)." Troup's statements, on which the finding is based, are contradicted by Schering's lead negotiator, Raman Kapur, who testified that there was no scientific discussion on the merits of Niacor-SR. CX 1511 at 71-72 (Kapur Dep.) (indicating no discussion of Niacor-SR's clinical results). Indeed, the Initial Decision fails to note that the discussions did not include Schering personnel with knowledge about niacin-related products. None of the Schering personnel involved in the recently terminated negotiations with Kos Pharmaceuticals were involved in the Upsher negotiations; Driscoll, the only person with firsthand knowledge of the Kos product, had dropped out of the negotiations with Upsher at this point.

In light of these shortcomings, the Commission has undertaken a de novo review of the record and substitutes the following findings for IDF 131-55. It is necessary to cite the testimony of many individuals. Throughout this opinion, we

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[77] To avoid any possible misunderstanding, we emphasize that we do not automatically discount testimony simply because it is self-serving. Most witnesses with knowledge of the facts have some stake in the outcome of a proceeding like this one – intellectual or emotional, if not financial. However, when the trial testimony of a strongly self-interested witness conflicts with the same witness's earlier testimony in a more unguarded moment, with contemporaneous documents, or with statements of less interested witnesses, it is necessary to take account of these alternative versions of the facts.

have identified the affiliations of all witnesses when they are first mentioned, and these identifications are also set out in an Appendix.

1. Findings of Fact on the Negotiations Between Schering and Upsher

In April or May 1997, Troup first approached Schering about a possible settlement of the patent litigation. Troup, Tr. 5397, 5407-09. The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation.

The initial settlement meeting took place between Driscoll and Troup at Schering's office in Kenilworth, New Jersey on May 21, 1997. Troup, Tr. 5409-10. This was the first of five face-to-face meetings between Schering and Upsher. Troup stated that his settlement objective was to obtain the earliest possible launch date for Klor Con M20 without incurring the damages that could arise from patent infringement. Troup, Tr. 5411-12. Driscoll recalled that Troup said in the initial meeting that the only way Upsher would settle the patent litigation was for payment of $60 million to $70 million and the ability to market within the year (an entry date). CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.). Driscoll recalled that the $60 million to $70 million was the estimated adverse impact on Schering of Upsher's entry and that Troup wanted a percentage of that impact. CX 1494 at 67 (Driscoll IH). It was value that Upsher had to have.[78] CX 1495 at 58

[78] Upsher's insistence on a payment persisted throughout the negotiations. See CX 338 (summary forwarded to the Schering Board when it approved the settlement agreement in issue, stating, "In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from the sales of Klor Con had they been successful in their suit.").

(Driscoll Dep.). Driscoll stated forcefully that Schering would not pay. CX 1494 at 66 (Driscoll IH); CX 1495 at 58 (Driscoll Dep.).

At this meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. Troup, Tr. 5412. Troup stated that Upsher wanted to be on the market at an earlier date and that it would have problems with cash flow if its entry were delayed until 2005. Troup, Tr. 5413. There is, however, no record support for Troup's claim of financial need (Kralovec, Tr. 5067), and Upsher disclaimed any intention to rely on it, in order to avoid disclosure of financial information during the discovery stage of this proceeding.[79]

The parties met again at Upsher's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Driscoll and Raman Kapur, President of Schering's Warrick subsidiary that markets generic drug products, attended these meetings on behalf of Schering. Troup and consultant Andrew Hirschberg attended on behalf of Upsher. Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions Nos. 7-9, 11-12; Upsher Second Admissions Nos. 9-10, 13-14, 22. At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher's generic products. Troup, Tr. 5420.

At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture where Schering would invest $14 million into Upsher's research and development efforts. CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34; USX 477 (Troup's contemporaneous notes of the June 3, 1997 meeting). They also discussed the possibility that Schering might license one or more Upsher products. The discussion during the May 28

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[79] See Part III, above.

meeting focused on settlement of the K-Dur litigation and there was a brief discussion of licensing cholestyramine (one of the generic products Upsher ultimately licensed to Schering as Prevalite) at the end of the meeting. CX 1511 at 14 (Kapur Dep.). The parties did not discuss Niacor-SR until the June 3 meeting and Upsher did not provide written material to Schering personnel at this meeting. CX 1530 at 70 (Troup Dep.); CX 1511 at 14 (Kapur Dep.); CX 1495 at 62 (Driscoll Dep.); CX 1511 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34.

Driscoll was aware of the market opportunity for Niacor-SR because he had been involved in evaluating the market for other, nearly identical projects. CX 1495 at 70-71, 73 (Driscoll Dep.). Troup was willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, because Upsher had no international presence. Troup, Tr. 5432.

During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. CX 1511 at 18-19 (Kapur Dep.). Troup stressed Upsher's need to replace the revenue it would lose if it did not have a generic K-Dur 20 product on the market. CX 1511 at 18-19 (Kapur Dep.).

During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher's entry with its generic version of K-Dur 20. CX 1511 at 22-23 (Kapur Dep.). Troup preferred an earlier date. CX 1511 at 23-24 (Kapur Dep.); CX 1529 at 100 (Troup IH); Troup, Tr. 5505-5507. The record evidence is unclear on who offered the September 1, 2001 date. Driscoll does not indicate, in either his investigation hearing or deposition testimony, that he offered a date earlier than 2005. Kapur recalled, however, that Driscoll told Upsher the earliest date he could offer for Upsher's entry was September 2001. CX 1511 at 23 (Kapur Dep.).

Regardless of who offered the September 1, 2001 entry date, the weight of the evidence indicates that the parties had not agreed upon the entry date of September 1, 2001 at the end of the June 3 meeting. Troup testified in his investigational hearing that the date had not been agreed to and that he would get back to Schering on the entry date after the June 3, 1997 meeting. CX 1529 at 100 (Troup IH). In his later deposition and trial testimony he stated that the date was settled by the end of the June 3, 1997 meeting, although he stated that he did not remember exact dates. CX 1530 at 82 (Troup Dep.). Hoffman, who attended his first meeting with Upsher personnel on June 12, testified both in his investigational hearing and on cross-examination at trial that the entry date was not even settled upon until after the next meeting on June 12, 1997. Hoffman, Tr. 3563; CX 1509 at 42 (Hoffman IH). Although Hoffman's direct trial testimony and deposition testimony are to the contrary, we find that his testimony on cross and the earlier investigational hearing is more credible. Therefore, we find that the negotiations on an entry date cannot be viewed as concluded by June 3, 1997, nor do we find that it was a matter separate and apart from other terms and provisions in the final agreement dated June 17, 1997.

Driscoll recalled that he ended his participation in the negotiations with Upsher after the June 3 meeting, even though he was head of the affiliate responsible for K-Dur. He stated that Troup wanted money to settle and Schering would not pay, so he decided to let the lawyers work it out. CX 1494 at 71-72 (Driscoll IH).

Before the parties' next face-to-face negotiation session, Hoffman spoke to Nick Cannella, Upsher's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. Cannella, Tr. 3824-25. Upsher representatives Troup, Cannella and Hirschberg, and Schering representatives Kapur and Hoffman, met in Kenilworth, New Jersey, on June 12, 1997. Troup, Tr. 5436-38; Hoffman, Tr.

3539, 3541-42. It is unclear from the evidence whether Jeffrey Wasserstein, Schering's Vice President of Business Development, attended this meeting. CX 1532 at 25-26 (Wasserstein Dep.); CX 1510 at 54 (Kapur IH) (Kapur indicating that only he and Hoffman attended the June 12, 1997 meeting).

The purpose of the June 12, 1997 meeting was to continue discussion of the potential for settlement of the lawsuit and the licensing of certain Upsher products. CX 1509 at 34 (Hoffman IH). The parties discussed a settlement proposal under which Schering would give Upsher a royalty-free license at some time before expiration of the patent, and the timing of entry would be based on the parties' potential for success or failure in litigation. CX 1509 at 34 (Hoffman IH). Hoffman indicated that Schering would not pay to settle the litigation. CX 1509 at 35 (Hoffman IH). Hoffman testified that Upsher's consultant (Hirschberg) provided an estimate of how much Schering stood to lose if Schering lost the suit. CX 1509 at 35 (Hoffman IH); Hoffman, Tr. 3544. There was agreement at the end of this meeting that the parties would settle the litigation, through a royalty-free license at some time prior to patent expiration, but no particular date had been picked. CX 1509 at 42 (Hoffman IH). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher's generic version of K-Dur. Troup, Tr. 5439; CX 1529 at 101-02 (Troup IH).[80] Troup stated at the June 12 meeting that Upsher still had "cash needs" because all of the company's cash was tied up in two products in development – Upsher's generic version of K-Dur and its similar sustained-release niacin product, Niacor-SR. Hoffman, Tr. 3543.

Before the June 12, 1997 meeting, Upsher required Schering to sign a confidentiality agreement regarding Upsher's

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[80] Upsher's own witness, Troup, apparently did not regard the entry date as settled, even as late as June 12.

Niacor-SR product information. CX 1041. Troup brought to the meeting a confidential printed presentation about Upsher's Niacor-SR product. Troup, Tr. 5436-37; CX 1042. This presentation was similar to the presentations Upsher provided to Searle and the European companies interested in licensing Niacor-SR. USX 538; CX 1023.[81] Troup also provided Schering with two draft protocols for conducting post-market studies of Niacor-SR. CX 714; CX 1043. Neither Kapur nor Hoffman had participated in the earlier negotiations with Kos on a niacin-related product. See Part IV.C.1, below.

Troup confirmed that Upsher's offer of a Niacor-SR license extended only to non-NAFTA territories. Hoffman, Tr. 3545; Troup, Tr. 5440-41. Schering was disappointed that Upsher would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. Troup, Tr. 5443-44. Kapur also expressed his

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[81] Through a consultant, Upsher contacted European companies to solicit interest in Niacor-SR. The first wave of contacts covered 32 companies. All but one of the companies in the first wave declined the opportunity or failed to respond. CX 888 (consultant's report summarizing responses received). The second wave of contacts covered additional smaller European companies. Four companies expressed interest in meeting with Upsher. Meetings with these four companies took place between May 28, 1997 and June 5, 1997. The meeting summaries assessed three of the potential licensees' interest as "moderate" or "low." CX 868 (Esteve meeting summary); CX 880 (Lacer meeting summary); CX 883 (Servier meeting summary). Only one partner, Pierre Fabre, was assessed as "moderately to highly interested," "if we can negotiate an acceptable deal." CX 881 at USL11826. That company expressed concerns in its meeting with Upsher about the safety of Niacor-SR, and questioned what kinds of payments might be involved because it had met with start-up companies that were asking "unreasonable payments of at least $50 million." CX 881 at USL11825-26. These tepid results were reported back to Troup. USX 1532 at 145 (O'Neill IH); Troup, Tr. 5570; USX 596-98; CX 880.

The other potential partner, Searle, "had no interest in further pursuing the product" because of questions about Niacor-SR's safety, in particular its toxicity profile. Egan, Tr. 7886.

continued interest in Upsher's cholestyramine and Pentoxifyilline products. Hoffman, Tr. 3545.

Troup made a brief presentation on Niacor-SR and brought written materials. Hoffman, Tr. 3544. Troup had not attended Upsher's presentations to other potential European partners, and none of the Upsher employees who had given the Niacor-SR presentation to other potential partners – including Halvorsen, Freese, and O'Neill – were present at the meeting with Schering. Troup, Tr. 5436-38; Hoffman, Tr. 3541-42. The parties discussed the market potential for Niacor-SR. Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868. Troup referred to Kos Pharmaceuticals' Niaspan product, its market capitalization and sales potential, to show that Upsher's Niacor-SR niacin product had tremendous potential. Troup, Tr. 5441-43; Cannella, Tr. 3829-30.

The June 12, 1997 meeting included a preliminary discussion of the price for the Niacor-SR product. Troup asked for $70-80 million in his first offer to Schering. Troup, Tr. 5449; Hoffman, Tr. 3545; CX 1511 at 44-45 (Kapur Dep.); Cannella, Tr. 3829. Troup did not base his asking price on Upsher's own estimates of the potential market for Niacor-SR. Upsher had not yet forecasted sales for the European/ex-U.S. markets, but its sales projections for the U.S. market were uniformly low.[82] A series of Upsher internal projections in 1996 and 1997 (before the Agreement) predicted sales in the $10 million range or below in the first year; the highest estimate was for $20 million in sales in the second year of one projection. CX 234 at USL12785, USL12797; CX 322 at 05287; CX 778 at 15531. As of September 1997, Upsher projected U.S. sales for Niacor-SR of only $9.6 million and

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[82] Troup testified that he considered the ex-U.S. market to be about the same size as the U.S. market. Troup, Tr. 5528. Kos, Searle, and Schering believed that the U.S. market potential was larger than the ex-U.S. market. CX 1470 at SP 002748 (Schering's Contact Report of April 9, 1997 describing meeting with Kos); Egan, Tr. 7915-16.

$11.5 million in its first and second years on the market. CX 1094 at 11935; see also CX 930 at 1319Γ (July 1997 projection of $7-8 million for Niacor-SR sales in 2003). These projections were based on Upsher's perception – based on actual sales data, not estimates – that the sustained-release niacin market had decreased in both dollar and volume terms. CX 929 at USL 13138 (March 1997).

Schering told Upsher it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher about its interest in pursuing a deal for Niacor-SR. Hoffman, Tr. 3545-46; Cannella, Tr. 3832. The parties also discussed potential licenses for other Upsher products, including Prevalite and Pentoxifylline (Troup, Tr. 5445-46; Hoffman, Tr. 3545), but these other products were not part of the deal at this point. Hoffman, Tr. 3545. The parties had not reached agreement on the settlement or licensing at the conclusion of this meeting. Hoffman, Tr. 3545.

Shortly before or after the June 12, 1997 meeting with Upsher in Kenilworth, Kapur and Driscoll briefed Schering's president of pharmaceuticals worldwide, Raul Cesan, on the Upsher negotiations. CX 1510 at 66-67 (Kapur IH); CX 1511 at 29-30 (Kapur Dep.). Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. CX 1511 at 30 (Kapur Dep.). Cesan asked Kapur to contact Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. CX 1511 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.).

In accordance with Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product that would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product

to see if it would be worth $60 million to Schering. Lauda, Tr. 4342-43. This is the same sum that Troup had demanded to settle the patent litigation.

Lauda asked James Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform a commercial assessment of Upsher's Niacor-SR product. Lauda, Tr. 4344. Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert might have. Lauda, Tr. 4404. Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware that the Niacor-SR opportunity had any connection to a patent suit. Audibert, Tr. 4113.

The final meeting between Schering and Upsher took place on June 16, 1997, in Upsher's office in Plymouth, Minnesota. Troup, Tr. 5452; Hoffman, Tr. 3550. Kapur, Hoffman, Wasserstein, and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher. Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834. The discussion again centered on the patent settlement and Upsher's claim that it needed cash flow to run its business. CX 1532 at 30 (Wasserstein Dep.). This testimony is confirmed by Hoffman, who recalled that Troup linked Schering's proposal for a license to take effect in the future with Upsher's cash needs in the interim. CX 1509 at 76 (Hoffman IH).

Discussion then turned to the valuation of the package of Upsher products, including Niacor-SR and Pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. Troup, Tr. 5453. Over the course of the meeting, Upsher offered to license its wax matrix 8 and 10 mEq products and Klor Con M20 to Schering for the ex-NAFTA countries. Troup, Tr. 5453. Troup still wanted $80 million. Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835. Schering made

a counter-offer of $60 million, which Upsher accepted. Cannella, Tr. 3835; Troup, Tr. 5458.

The parties discussed, either at the June 16 meeting or shortly thereafter, that the $60 million would be paid in installments. Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511 at 74-75 (Kapur Dep.). To bridge the gap between Upsher's asking price and Schering's counter-offer, the parties negotiated additional milestone payments for launch of Niacor-SR in nine different countries throughout the world, including $2 million for Japan and $1 million each for eight other countries, totaling $10 million in milestones. CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr. 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59. (These milestones were never reached, and the payments were not made.) Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to $50 million and a 15% royalty on annual net sales in excess of $50 million. Troup, Tr. 5459; CX 347 at SP 12 00195.

Audibert completed his commercial assessment of Niacor-SR on June 17, 1997, one day after the final face-to-face meeting. SPX 2. Audibert and Lauda may have discussed Audibert's assessment before Audibert completed it (Lauda, Tr. 4345; CX 1483 at 30 (Audibert IH)), but the record evidence is unclear on when or how the results of the assessment were communicated to the team (Kapur, Hoffman, Wasserstein, or Thompson) negotiating with Upsher. The documentary evidence shows that Audibert's assessment was faxed to Kapur on June 17, 1997, one day after the parties agreed to the $60 million term. Lauda testified that there was no urgency to the commercial assessment, and he did not work on it over the weekend (June 14 and 15). Lauda, Tr. 4383; CX 1515 at 103 (Lauda IH). Audibert did not have discussions with Kapur or Wasserstein before completing the assessment. CX 1484 at 103 (Audibert Dep.). Wasserstein did not recall what analysis had been completed by the time of the June 16 meeting or who

told him about the financial assessment of Niacor-SR, although he recalled that the team knew the information and it was an assumption going forward. CX 1531 at 67-68 (Wasserstein IH). The results of this assessment are discussed below.

2. Factual Conclusions About the Negotiations

These specific findings demonstrate that, throughout the settlement negotiations, Upsher made the connection between delayed entry and the payment of money by Schering. At every negotiation session, Troup demanded compensation in return for an agreement on an entry date. Moreover, the negotiations on entry date were not concluded by June 3, 1997, and agreement on the entry date was directly linked to agreement on the other terms and conditions in the June 17, 1997 contract. Schering fully understood the essence of Upsher's demand for money in return for delay, and was aware that an outright payment for delay raised legal problems. Schering relied on the Upsher licenses to provide an ostensible justification for the $60 million payment.

The record as a whole further demonstrates, however, that the Schering participants in the settlement negotiations (Kapur, Hoffman, Wasserstein, and Thompson) were not knowledgeable enough about the products licensed from Upsher to determine for themselves whether the Upsher licenses were worth the payments agreed upon. We now turn to the question whether, notwithstanding their unfamiliarity with the safety, efficacy, and commercial aspects of the licensed products at issue, there is other evidence from which to determine whether the Upsher licenses likely were worth $60 million.

C. Schering's Internal Evaluation of the License Opportunities

To understand whether the license for Niacor-SR was worth $60 million to Schering,[83] it is important to place the license in the context of Schering's efforts to license another sustained-release niacin product from Kos Pharmaceuticals ("Kos") in the first half of 1997. Various Schering personnel devoted substantial time and resources to an evaluation of Kos's Niaspan product and its market opportunities. Like the Initial Decision (IDF 201-61), this section discusses both what Schering learned about sustained-release niacin during the Kos negotiations, and Schering's evaluation of the Niacor-SR license. For the reasons summarized immediately below, however, the discussion of these issues in the Initial Decision is seriously flawed and it is necessary for us to substitute our own factual findings.

The Initial Decision relies primarily on the direct testimony of two individuals – Raymond Russo, the marketing director of Schering's Key division for cardiovascular products in the United States, and James Audibert, Russo's counterpart for territories outside of the United States – for a description of the negotiations between Schering and Kos about the Niaspan opportunity. Although Russo led Schering's negotiations with

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[83] The evidence is clear that the $60 million payment related to Niacor-SR, and that the other products were "throw-ins" and not separately evaluated as consideration for the Agreement. CX 1511 at 63 (Kapur Dep.); id. at 93-94 ("the deal was for Niacor"); CX 1530 at 89 (Troup Dep.); Troup, Tr. 5594-95; CX 1510 at 71-72 (Kapur IH) ("Q. [illegible]ne $70 million value just for the Niacor license? A. Yeah. Everything else was sort of a flow in, basically for the Niacor product."); CX 1[illegible]5 at 86-87 (Lauda IH) (Lauda was told that Niacor-SR's profitability would have to be enough to warrant a $60 million up-front payment); CX 338 (presentation to Schering Board of Directors describes the other licenses as "less significant" than Niacor-SR; there is no NPV calculation for those licenses); Hoffman, Tr. 3562, 3569 (recognizing that Niacor-SR was the main licensing opportunity).

Kos from February 1997 through June 1997, Audibert did not participate in the meetings with the Schering team after the end of March or early April 1997. Thus, to the extent Audibert is the source for facts beyond the date his participation ended (e.g., IDF 208 and 242), the Commission has substituted its own findings from more reliable sources.

The Initial Decision also fails to consider the testimony of Driscoll, who was Russo's supervisor and was responsible for terminating the negotiations with Kos in June 1997, based on Niaspan's safety and efficacy issues and its limited commercial potential. The Commission finds Driscoll's testimony, and his memorandum dated June 9, 1997, which summarizes the commercial and product safety- and efficacy-related reasons for ending the Kos negotiations (CX 558), more probative than the deposition and direct testimony of Russo, Audibert, and Lauda (recited in IDF 207-08, 219, 242, 255, 258).

The Initial Decision also does not give adequate weight to other contemporaneous business documents that provide reliable and probative evidence of the events during the Kos negotiations. In particular, the Initial Decision does not rely on the contact reports (i.e., internal summaries of the conference calls or meetings) between Schering and Kos personnel of March 13 (CX 577), April 9 (CX 1047), and May 21, 1997 (CX 557); Russo's memorandum of March 26, 1997, describing the negotiations to date and issues to be resolved going forward (SPX 21); and Audibert's March 14, 1997 questionnaire to Schering's international subsidiaries (CX 544).

Similarly, the Initial Decision fails to appreciate the implications of Schering's own market research on sustained-release niacin products (CX 576; SPX 231 (in camera)), and Schering's inexplicable failure to take account of that research when it evaluated Upsher's Niacor-SR product. For example, Schering's own domestic market research on sustained-release niacin in April 1997 contained nine conclusions that raise significant concerns about the commercial potential for

Niaspan. CX 576. The Initial Decision's only reference to this market research is one phrase contained in one of the conclusions. IDF 211. This one statement is not representative of the other seven conclusions in the report. The Initial Decision also fails to consider fully what the conclusions in Schering's European market research (SPX 231 (in camera) suggest about opportunities for cholesterol drugs in Europe. See IDF 235-36.

Schering relied heavily on the calculations of Audibert to support its claim that the payment to Upsher was reasonable, but the Initial Decision mischaracterizes the task that Lauda asked Audibert to perform. Rather than conducting "an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity" (IDF 243), Audibert simply responded to a request that he produce a sales forecast and a profit and loss statement for Niacor-SR. To the extent the Initial Decision implies that Audibert evaluated the safety and efficacy of Niacor-SR (see, e.g., IDF 247), the Commission disregards it.

The Initial Decision relies on Audibert's direct testimony to prove that the Niacor-SR license was worth $60 million, without weighing it against the knowledge that Schering had acquired through its domestic and European market research (CX 576; SPX 231 (in camera)) and the reservations that Schering personnel had expressed about sustained-release niacin (CX 558). See, e.g., IDF 249 (discussing Schering's own market research that showed a product with a profile similar to Niacor-SR would not be well received as a monotherapy); IDF 239-41 (detail regarding what Audibert learned about the safety and efficacy of sustained-release niacin through the Kos negotiations).

Because of the Initial Decision's failure to take adequate account of various probative documents and its misplaced reliance on testimony of certain individuals, the Commission

substitutes the following findings for the findings in IDF 201-61.

1. Findings of Fact on Schering's Evaluation of Kos's Niaspan

a. Schering's Research into Kos's Niaspan Product

Kos filed an NDA for Niaspan with the FDA in May 1996. SPX 18 at 002776. Schering was interested in Niaspan in early 1997. Driscoll believed that a sustained-release niacin product "that met the unmet needs that existed in the marketplace could be big." CX 1494 at 85 (Driscoll IH); see also CX 1495 at 73 (Driscoll Dep); Audibert, Tr. 4116-17. Driscoll also stated that Schering was interested in niacin primarily as a complementary agent to statins, the primary pharmaceutical compounds used to treat high cholesterol. CX 1494 at 86 (Driscoll IH).

Other Schering personnel stated they were interested in Niaspan not only as a late-stage product that could generate revenues in the near term, but also because Niaspan presented an opportunity for Schering to sell a cholesterol-lowering product in advance of its launch of ezetimibe, a drug that Schering was developing for the same purpose. Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771 (Russo's memo outlining Niaspan opportunity).

In February 1997, Schering distributed to members of its Cardiovascular Licensing Group a confidential information package provided by Kos in connection with the Niaspan opportunity. SPX 924. This package contained overview information on Niaspan, a copy of its proposed labeling, and a published report of a clinical study conducted with Niaspan.

In 1997, Russo was Key's marketing director for cardiovascular products in the United States. Audibert, Tr. 4109-10; Russo, Tr. 3409-10. Russo led the negotiations with

Kos on its Niaspan product. Russo, Tr. 3449. Driscoll supervised Russo. CX 1494 at 88 (Driscoll Dep.). Audibert was Russo's counterpart, responsible for territories outside the United States, and was for a time involved in the negotiations with Kos regarding Niaspan. CX 1483 at 77-78 (Audibert IH); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439.

By the time of Schering's negotiations with Kos, the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. Russo, Tr. 3445; Audibert, Tr. 4102, 4105. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. Russo, Tr. 3449; CX 577 at SPCID2 1A 00110 (Schering's March 13, 1997 report of contact with Kos). This arrangement differs from one in which the company that took a license would retain all control and all sales proceeds after royalties are paid. Russo, Tr. 3449-50.

Schering and Kos personnel communicated by conference call on March 13, 1997. Russo, Audibert, and Karin Gast, Director of Business Development, participated on behalf of Schering; Daniel Bell, President and CEO, and others participated on behalf of Kos. CX 577. Audibert wanted to find out whether Niaspan had a better side effect profile than immediate-release niacin, especially in the areas of flushing and itching. CX 1484 at 39 (Audibert Dep.). He also had concerns about hepatotoxicity. CX 1484 at 39-40 (Audibert Dep.). Audibert indicated that he wanted to see data from clinical studies (CX 1484 at 45 (Audibert Dep.)), and he wanted to see the charts and study reports with information on safety and efficacy. CX 1484 at 57 (Audibert Dep.). Kos did not provide this information to Schering. CX 1484 at 59 (Audibert Dep). Audibert's deposition testimony is corroborated by Schering's contact report prepared by Gast summarizing the call, in which Audibert "in particular wanted

to know what is the safety profile for Niaspan." CX 577 at SPCID2 1A 00109.

Kos's labeling also made statements about reduced risk of hepatotoxicity development with its compound, but Kos was unwilling to share any information to verify the claim. CX 1495 at 128-29 (Driscoll Dep.). Schering asked Kos for more information, including Niaspan's clinical results that supported the label claims. CX 1495 at 96 (Driscoll Dep.). In Driscoll's view, the data that Kos did provide Schering (CX 924) showed that the incidence of flushing in the pivotal clinical trial was too high. CX 1494 at 85-86 (Driscoll IH). In addition to the safety and side effect profile information that Schering did not receive, Schering also did not receive Kos's market research on physician interest in a sustained-release niacin product. CX 1494 at 89 (Driscoll IH); CX 1495 at 100 (Driscoll Dep.).

One day after the March 13, 1997 conference call with Kos, Audibert sent a questionnaire to Schering's international subsidiaries that inquired about their interest in sustained-release niacin and sought information about cholesterol treatment in their countries. He does not recall whether he received any responses. CX 1484 at 52-53 (Audibert Dep); CX 544. After sending this questionnaire to Schering's international subsidiaries, Audibert did not participate further in negotiating with Kos. CX 1484 at 76-77 (Audibert Dep.).

On March 26, 1997, Russo prepared a memorandum summarizing four outstanding issues that had to be resolved for the Niaspan opportunity to be viable. Russo, Tr. at 3495-96; CX 546. These included: (a) a guarantee that Schering would have input into promotional and strategic efforts; (b) an equitable method to recognize revenue; (c) due diligence regarding patent status, final labeling, manufacturing capabilities, and product liability; and (d) Schering's evaluation of the commercial potential of the product, which included an assessment of the product's worldwide potential. CX 546. Russo "assume[d] that the safety profile, levels of liver toxicity,

side effects, and approved indications would be consistent with the proposed labeling included in the Kos package." CX 546 at 2770. Schering "would of course subject any deal to this [sic] criteria." CX 546 at 2770.

On April 9, 1997, Schering personnel (Russo, Toni DeMola, Gast, and David Grewcock) visited Kos Pharmaceuticals to discuss the Niaspan product opportunity and the issues in the March 26, 1997 Russo memorandum. CX 1047. The contact report summarizing the meeting states that Kos knew "that Niaspan will have to overcome some rather negative perceptions about niacin within the patient/medical community and that it is very important that the product get on managed care formularies." CX 1047 at SP 002747. The contact report also notes that Dan Bell "realizes that the market potential [of Niaspan] in Europe (and probably also in Japan) is quite limited." CX 1047 at SP 002748.

Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. Russo, Tr. 3455. Part of that process involved an assessment of the product's value to Schering, and Russo produced three sales scenarios – a "base" case, an "upside" forecast, and a "downside" forecast for the years 1997 through 2007. Russo, Tr. 3456. He then priced each of these three scenarios under two different sets of pricing assumptions (a higher price and a lower price), so that, in total, he created six different sales forecasts. Russo, Tr. 3457; CX 550.

According to the sales forecast documents, Russo proceeded through multiple steps to arrive at the projected sales figures. CX 550. He first projected the overall U.S. population for each year, and then estimated through third-party data the percentage of patients that are likely to be managed with a prescription for lipid disorders. He then examined the total eligible patient population and how many of these patients would likely receive a prescription of any kind. He assessed what he thought Schering's position would be in the market for

niacin. He made estimates for sales and promotion to expand the market. Russo, Tr. 3458. He then determined how many patients would be treated with niacin and how many of those patients would be treated specifically with Niaspan. Russo testified that, under his most realistic scenario, projected sales in the United States were $134 million in 2002, rising thereafter to $193 million, based on the co-promotion deal under consideration with Kos. Russo, Tr. 3457-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731.

Schering's market research in the United States included efforts to determine physician interest in sustained-release niacin. Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576. A market research report entitled "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders – Telephone Interviews with Lipid Specialists" (Apr. 1997) contained nine conclusions. Six of the conclusions[84] are: (1) The 10 experts tend to be strong supporters of niacin, as opposed to general practice physicians that tended to avoid niacin. These experts point out that niacin "does all the right things" to manage lipids. (2) The experts avoid use of sustained-release niacin because of diminished efficacy and concern regarding liver toxicity. The experts pointed out that successful use of niacin requires a very motivated physician as well as patient, and that expanding niacin use will require a major commitment to physician and patient education. (3) Most niacin use is in combination with a statin, which has become the mainstay of lipid management, but several experts commented that this adjunctive role may lessen as new products are used. (4) The fibric acids (a competitor to niacin) are widely used in Europe, and several physicians reported being quite impressed with fenofibrate. (5) Although the experts would welcome an effective, safe, FDA-approved

[84] The other three conclusions discuss the relative merits of altering levels of particular components of total lipids as treatment methods.

sustained-release niacin, the single study Schering discussed with them did not sell them on Niaspan and they needed larger, longer studies and trials in combination with a statin to be convinced on the safety issue. (6) Physicians voiced numerous concerns and questions about safety, side effect claims, and use with a statin, and they need "compelling evidence" to support the safety and side effect claims, which "go against our experience" with niacin. A successful sustained-release niacin product will take time and "a significant promotional investment." CX 576 at SP 020709-12.

In the spring of 1997, Audibert began coordinating with Schering's European subsidiaries to establish an advisory panel with European experts in cholesterol management to obtain market research about its cholesterol drug in development – ezetimibe. Audibert, Tr. 4301-02 (in camera); SPX 221 at SP 002895-2898 (in camera). This panel concluded that a large market for the product does not exist unless it is "very inexpensive and very safe." SPX 231 at 002949.

b. Termination of Schering's Negotiations with Kos

On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. Russo, Tr. 3463-64; CX 554 (in camera); SPX 619. Schering is the only company that gave Kos a written proposal before Niaspan was launched. Patel, Tr. 7543. Schering proposed to Kos a co-promotion arrangement in which both companies would sell and market the product together. Russo, Tr. 3589 (in camera); CX 554 (in camera). Schering proposed a 50/50 profit and loss split (Russo, Tr. 3589-90 (in camera); CX 554 (in camera); Patel, Tr. 7665 (in camera); SPX 619 (in camera)) and also suggested that it would give Kos a 10% to 15% royalty payment on the total sales of its product. Russo, Tr. 3589-90 (in camera); CX 554 (in camera). One week after submitting its proposal, Schering had a conference call with Kos to discuss the written

proposal. SPX 230; SPX 35 (in camera); Patel, Tr. 7667 (in camera). Kos did not react favorably to Schering's proposal. Russo, Tr. 3465. Bell, the Chief Operating Officer of Kos, told Schering representatives that its offer was practically "insulting," and that he was "offended" by it. SPX 230; Patel, Tr. 7669 (in camera). A major problem for Kos was Schering's failure to offer an up-front payment. Kos also wanted very significant milestone payments, to compensate for its research and development costs, and to reassure Kos that Schering was committed to the venture. Patel, Tr. 7531-32; CX 556 (in camera); CX 769 (in camera); Russo, Tr. 3465-66. After receiving Kos's reaction to its first proposal, Schering did not submit another proposal. Russo, Tr. 3466, 3488; CX 558.

On June 9, 1997, Driscoll recommended to his superior, Richard Zahn, that Schering discontinue discussions with Kos. CX 558. Driscoll explained in the memorandum that "the principal reason" for discontinuing negotiations was that the opportunity was not large enough to warrant distraction from Key's core businesses. He did not share the view of the outside investment analysts who indicated that the Kos product was a $250 million product. He estimated a peak year of $134 million in 2002 with a 10-year net present value of $420 million. Driscoll pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduced niacin side effects of flushing and hepatotoxicity. He noted that Niaspan's labeling "indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing." CX 558 at 2719. He also explained that statins have taken a large share in the market, and that generic statins would be available in the U.S. in 1999, which could affect sales of a lower-priced niacin product such as Niaspan. Driscoll concluded there was a wide gulf on expectations. CX 1495 at 123-24 (Driscoll Dep.).

2. Findings of Fact on Schering's Evaluation of Upsher's Niacor-SR

In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product that would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product. Lauda, Tr. 4342-43. It is unclear from the evidence how Kapur knew that the licensing opportunity would cost $60 million. Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide Ex-NAFTA"). Lauda, Tr. 4344.

Audibert was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. Audibert, Tr. 4085, 4092. His responsibilities included work on ezetimibe, the cholesterol-lowering agent Schering had in development. Audibert, Tr. 4093. By early 1997, Audibert began working with Schering's research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. Audibert, Tr. 4094. As part of this process, Audibert was also evaluating the market for cholesterol-lowering drugs. Audibert, Tr. 4094-95.

Lauda specifically asked Audibert to develop a sales forecast and a profit and loss statement for Niacor-SR based on the information provided in a 52-page data package. CX 1484 at 109-10 (Audibert Dep.). Audibert began his review when he received this data package on Niacor-SR on Thursday afternoon, June 12, 1997, and completed his work on Tuesday morning, June 17, 1997. Audibert, Tr. 4113, 4163; Lauda, Tr. 4344-45. The package included summary results from the two phase III pivotal clinical trials conducted by Upsher to obtain registration of Niacor-SR. Audibert, Tr. 4113-15, 4171; CX

1042; Halvorsen, Tr. 3907-08. The package also included information on two draft protocols for phase III-B studies that Upsher was planning to conduct once the NDA was filed. Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025. One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. Audibert, Tr. 4115; SPX 71-72.

The clinical data from Upsher's pivotal trials showed that Niacor-SR reduced LDL cholesterol between 15% and 20%. Audibert, Tr. 4123; CX 1042 at SP 1600082, SP 1600097. This reduction is comparable to that resulting from use of Niaspan. CX 924 at SP 002789, SP 002792. Both the Niacor-SR and Niaspan reductions exceeded the 15% regulatory hurdle, but were less than the 20% reduction that Schering's market research indicated would be necessary to market the product as a monotherapy. SPX 231 at 002944-45 (in camera). Upsher's summary clinical data for Niacor-SR showed that the overall incidence of flushing was comparable to that of Niaspan. Compare SPX 3 at 160088 (on Niacor-SR) with SPX 924 at SP 002809 (on Niaspan). Moreover, the Upsher data showed that even though the number of flushing occurrences was lower, on a per patient basis, than with immediate-release niacin (see SPX 3 at 16 00089 (graph at top of page) and Audibert, Tr. 4118-19), the occurrences were just as severe as those experienced among patients taking immediate-release niacin. SPX 3 at SP 16 00088 (graph at top of page).

The clinical data from Upsher's pivotal trials showed that adverse effects on the liver increased with stronger doses of Niacor-SR. CX 1042 at SP 1600090; CX 1483 at 73-74 (Audibert IH). Audibert testified that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that of cholesterol-lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained-release niacin products. Audibert, Tr.

4104-05, 4121-24. Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. Audibert, Tr. 4121-22; CX 1042 at SP 16 00093. These results are comparable to the information that Schering had when it had evaluated Kos's Niaspan product. See SPX 924 at SP 002811.

Audibert constructed a forecast of sales based on the product's profile in the market. Audibert, Tr. 4124. The process for constructing this sales forecast included: (1) a determination of the current and future sizes of the cholesterol-lowering market; (2) a determination of how Niacor-SR would be positioned within that market; (3) a determination of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. Audibert, Tr. 4124-27.

First, Audibert determined the current size of the market and made a projection of the future growth of that market for a period of 10 years based on IMS data representing the current size of the cholesterol-lowering market worldwide, excluding the U.S., Canada and Mexico ("Worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. SPX 5; CX 1483 at 109-10 (Audibert IH). The IMS data indicated that the size of the cholesterol-lowering market in those territories in 1996 was $4 billion. SPX 5. Audibert's handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. SPX 5 at SP 16 00447. Audibert estimated an average annual growth of 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. SPX 2 at SP 16 000046. Audibert projected the market share Niacor-SR could achieve based on his experience with this type of product and this type of profile, given the existing competitive landscape. CX 1483 at 100-02 (Audibert IH). Audibert

believed that Niacor-SR would obtain an initial market share of only .75%, rising for just two years to 1.5%, and then decreasing thereafter to 1%. Audibert, Tr. 4127-29; SPX 2 at SP 16 00047.

Having estimated the overall size of the market and a market share for this product over a 10-year period, Audibert used multiplication to determine projected sales. Audibert, Tr. 4127. Audibert's formal written assessment for Niacor-SR, dated June 17, 1997, includes tables illustrating his annual projections of market size and market share, from which he calculated annual dollar sales. Audibert, Tr. 4127-29; SPX 2 at SP 16 00046-47. The sales projected for each of these years, in millions, were:

Sales ($)	1999	2000	2001	2002	2003
Millions	45	70	114	126	116
	2004	2005	2006	2007	2008
	127	140	125	136	149

SPX 2 at SP 16 00047.

On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. Audibert, Tr. 4138-39; SPX 6. The annual profit and loss calculations were created by deducting the cost of goods sold (estimated at a standard 10% of sales) from his sales forecasts (CX 1483 at 115-16 (Audibert IH)), as well as deducting the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at $22.8 million in the third year of sales. SPX 6. Because Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher. Audibert, Tr. 4139.

After Audibert developed the commercial assessment (SPX 2; SPX 6), he summarized the information contained in the 52-page data package without independently verifying it. CX

1483 at 95-96 (Audibert IH). Audibert provided background information on cholesterol-lowering products, including the current state of knowledge on niacin as an effective cholesterol-lowering agent, as well as the difficulties that had hampered prior immediate-release niacins (flushing) and sustained-release niacins (association with hepatotoxicity). SPX 2 at SP 16 00041-45. Audibert detailed the current size of the cholesterol-lowering market and the recent growth experienced in that market, and provided an assessment of why that growth was expected to continue. SPX 2 at SP 16 00043-45. He concluded that a product opportunity existed for Niacor-SR, and he provided a summary of his sales projections for Niacor-SR. SPX 2 at SP 16 00045. He attached to his assessment two tables that contained his detailed financial projections of both the future growth of the cholesterol-lowering market and sales of Niacor-SR in that market. SPX 2 at SP 16 00046-47. Audibert concluded that Niacor-SR offered a $100+ million sales opportunity for Schering. SPX 2 at SP 1600045. He provided a copy of each of these documents to Lauda. Audibert, Tr. 4138-40; Lauda, Tr. 4345-46.

On the basis of the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher called for under the agreement, Wasserstein prepared a presentation for the Schering Board. SPX 26. The presentation included a calculation which indicated that Niacor-SR yielded an economic value to Schering of between $225 to $265 million, and an internal rate of return of 43%. SPX 26 at SP 16 00275.

3. Factual Conclusions on Schering's Investigation of Niaspan and Niacor-SR

We do not find that Schering's failure to pursue the Kos opportunity is conclusive evidence that it was not really interested in the Upsher product. There were deal-specific

reasons that contributed to Schering's rejection of the Kos co-promotion opportunity. However, the Kos negotiations did inform several Schering personnel about the commercial problems of sustained-release niacin products – information that we need to weigh in determining whether Schering really paid $60 million for the rights to such a product.

Schering's decision to decline an opportunity to co-promote Kos's Niaspan product was made only the week before the negotiations for Niacor-SR were completed on June 17, 1997. Driscoll's June 9, 1997 memorandum to his supervisor, Richard Zahn (on which he copied all of the members of Schering's Kos negotiating team), recommended that Schering discontinue negotiations with Kos and described these commercial problems in detail. CX 558. Driscoll wrote that "the principal reason" for discontinuing the negotiations with Kos was "based on our current assessment that Niaspan does not represent a large-enough opportunity in the marketplace, thus, sufficient revenues would not be available to Schering-Plough to warrant our involvement and distraction from our core businesses." CX 558 at 2719; see also SPX 56. Driscoll calculated the NPV based on the co-promotion proposal for the U.S. market and found that the expected gain would not warrant Schering's involvement, even "without consideration given to the 'lost opportunity sales' we would experience with our current brands due to our shift in promotional focus away from these products to support the marketing of Niaspan." CX 558 at 2719.[85]

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[85] IDF 221-26 suggest that Kos was unable to enter into an agreement with a licensing partner because Kos's demands were unreasonable. Whatever the truth of the proposition that Kos was aggressive in its negotiations with potential partners, Kos has not been able to license Niaspan to any ex-U.S. partner, much less obtain an agreement as lucrative as the Upsher/Schering agreement. Patel, Tr. 7540. Moreover, Schering's primary reason for terminating its own negotiations with Kos was concern about the sales prospects of Niaspan – and it was not alone in these concerns. Egan, Tr. 7913-14 (Searle's view).

Driscoll then evaluated the commercial opportunity for niacin in a market increasingly dominated by statins. Lipitor had been introduced and had a "torrid start." CX 558 at 2720. Based on Lipitor's potency and "seemingly benign side-effect profile," Driscoll stated that the need for a niacin product in combination with another cholesterol-lowering product was "greatly reduce[d]." CX 558 at 2720. According to the memorandum:

> Niaspan could be relegated to the severe hypercholesteremic patients who need a multiple drug regimen. As a result, Niaspan's market opportunity is narrowing even prior to its introduction. Indeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor.

CX 558 at 2720 (emphasis added).

Although the deal contemplated with Kos was not exactly the same as the deal with Upsher – the Kos deal was to be a cross-promotion, where Kos and Schering would split the profits – Schering's view that the product had limited potential in the U.S. market transcends the specific terms of these deals. Driscoll pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduces niacin side effects, flushing and hepatotoxicity. He stated that "it is important to note" that Niaspan's labeling "indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing." CX 558 at 2719; SPX 924 at SP002809.[86]

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[86] By comparison, the summary clinical data that were provided to Audibert showed flushing incidence of 87%, 81%, and 87% for three different dosages of Niacor-SR. SPX 3 at 16 0008"; Audibert, Tr. 4118 (explaining that column A is for immediate-release, while B, C, and D are Niacor-SR dosages).

Upsher's summary clinical data for Niacor-SR showed that reduction in cholesterol and the incidence of flushing were comparable to those for Niaspan. Schering's pharmaceutical expert, Dr. Zola Horovitz, testified that the summary tables in the 52-page data package show that Niacor-SR was more effective than immediate-release niacin (Horovitz, Tr. 3642-43), and more benign than immediate-release niacin in terms of flushing (Horovitz, Tr. 3645-46) and liver enzyme elevation. Horovitz, Tr. 3632-35, 3649-51. It would be more appropriate, however, to compare Niacor-SR with Niaspan and specifically to take account of what Schering personnel who had worked on Niaspan believed were its commercial prospects. Driscoll's June 9, 1997 memorandum, discussed above, is a credible expression of their view, and we find that their expressed reservations about the safety and efficacy of Niacor-SR are more persuasive than Dr. Horovitz's opinions.[87]

One incident in the course of Schering's discussions with Kos is also particularly probative. Schering personnel saw the U.S. market as more appealing than the European market, for which Schering later obtained the Niacor-SR rights. According to a Schering summary of a meeting with Kos on April 9, 1997, Schering recommended that it made sense to focus on the U.S. market first and hold off on ex-U.S. talks:

> Global option: we suggested that, since time is of the essence in the U.S., we concentrate on this territory first and leave ex-U.S. discussions for later. [Kos CEO] Bell did not have a problem with this. He realizes that

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[87] Upsher, too, recognized that the market opportunity for a sustained-release niacin product was narrowing. In March 1997, Upsher noted that the "total niacin market has been relatively flat in dollars while increasing 35% in units." CX 929 at USL 13138. In fact, the sustained-release niacin market had "declined 14% from the previous year" in dollar terms, and 7.7% in volume terms. Id.

> the market potential in Europe (and probably also in Japan) is quite limited.

CX 1470 at SP 002748(DeMola/Russo memorandum dated 4/9/97). As this memorandum makes clear, both Kos and Schering shared the view that the European market for this type of product was less commercially appealing than the U.S. market.[88]

Schering's careful scrutiny of the Kos opportunity also shows the type of information Schering personnel thought was necessary for a prospective partner to provide before proceeding with a commercial opportunity for a sustained-release niacin product. In his memorandum explaining the reasons for declining the Kos opportunity, Driscoll wrote that Kos had not been forthcoming with important data necessary to fully evaluate the deal, such as its sales projections for Niaspan and "results from physician primary research conducted by Kos." CX 558 at 2720. Yet Schering did not even request sales projections or primary research relating to Niacor-SR from Upsher.

Similarly, Russo's memorandum of March 26, 1997, which set out the hurdles that needed to be cleared before an opportunity with Kos could be finalized, concluded that "[f]or this [Niaspan] opportunity to be viable for [Schering] a number of issues must be resolved," including "due diligence validation of issues" such as patent status, finalized labeling, manufacturing capabilities, and product liability. SPX 21 at 002770. Schering would also "need to independently assess this product's world-wide potential," including "global potential, Managed Care impact, and strategic synergy with 58235 [a product then in development], and field force availability/fit." SPX 21 at 002771. Aside from Audibert's projection of Niacor-SR sales, none of these tasks were

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[88] Searle also shared this view. Egan, Tr. 7915-16.

undertaken with respect to Niacor-SR. Moreover, Russo "assume[d] that the safety profile, levels of liver toxicity, side effects, and approved indications would be consistent with the proposed labeling included in the Kos package. We would of course subject any deal to this [sic] criteria." SPX 21 at 002770 (emphasis added). By contrast, Schering's agreement with Upsher was not conditioned on validation of any representations or on any regulatory benchmarks.

Schering's own domestic market research showed that physicians had numerous concerns and questions about the safety, side effect claims, and use with a statin of sustained-release niacin. Physicians also needed "compelling evidence" to support the safety and side effect claims that "go against our experience" with niacin. The research showed that a successful sustained-release niacin product would take time and "a significant promotional investment." CX 576 at SP 020709-12.

Lauda had given Audibert, who had participated only briefly on the Schering team that evaluated Niaspan, the task of estimating Niacor-SR sales. The work that Audibert did to arrive at his sales forecasts was not nearly as extensive or as refined as the work that Russo did in his sales forecasts of the Niaspan opportunity with Kos. Russo based his sales forecasts on an analysis of the eligible patient population within the U.S., whereas Audibert used aggregate ex-U.S. sales as his starting point. Audibert did not examine eligible patient populations on a country-by-country basis as Schering's expert witness, James Furniss, testified he would have expected Schering to do. Furniss, Tr. 4273. Furniss testified that a more detailed, country-by-country analysis of a late-stage product such as Niacor-SR is important because each country has a different pricing reimbursement system and some products may be widely prescribed in one country and not in another. Furniss, Tr. 4270-71. Moreover, in contrast to Russo, who had prepared six different forecasts under various pricing assumptions for Niaspan, Audibert prepared only one sales forecast with no

allowances for different market penetration statistics or pricing scenarios.

Audibert received the Upsher materials on which he based his commercial assessment no earlier than 4:30 p.m. on Thursday, June 12. He faxed the completed commercial assessment and profit and loss statement on Tuesday, June 17, at 9:30 a.m. Audibert said that the tasks he performed would take "maybe a little bit more but not – not much more" than one day to complete. Audibert, Tr. 4164. During this 5-day period Audibert did not contact personnel at Upsher to determine when the draft protocols would be started or completed, or to request the labeling for the product. Audibert, Tr. 4172-75; CX 1484 at 91-92 (Audibert Dep.). He did not contact any members of the Schering team that had just terminated discussions about Niaspan with Kos on June 9, 1997. CX 1483 at 50-52 (Audibert IH); Audibert, Tr. 4168. Instead, he based his commercial assessment on the information about Niacor-SR provided to him by Upsher. Audibert did not independently verify any of the information in the 52-page data package. He said that he based his assessment on what the product would be (i.e., labeled for once-a-night dosing and administered in combination with other cholesterol products), not on what clinical tests had been done so far. Halvorsen, Tr. 4025; CX 917 at 107435; Audibert, Tr. 4172-76, 4196-97. He simply assumed that Niacor-SR would be approved for these indications even without completion of the additional clinical tests. Audibert, Tr. 4173.

These assumptions stand in direct contrast to Audibert's skepticism about the Niaspan product, for which he and Driscoll had demanded additional information to verify Kos's claims.[89] He was more cautious about Niaspan, even though

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[89] The 52-page data package that Upsher provided to Schering contained information that is similar to what Kos had provided to Schering regarding the Niaspan opportunity. CX 1042 at SP1600081-85, 94; SPX 924.

Kos was much further along in obtaining approval for the indications that were of interest.

Based on the record as a whole, we find that Schering knew sustained-release niacin had significant unresolved safety issues, limited market appeal in the U.S., and even less outside of the U.S. Even if we assume that Schering had only five days to review the Niacor-SR product,[90] it could have done much more – in parallel with Audibert's work on the commercial sales projection – to ascertain whether Niacor-SR merited such a substantial, unconditional investment. For example, nobody at Schering was assigned to evaluate the likelihood of obtaining regulatory approval for Niacor-SR in the U.S. or in Europe, to examine Upsher's regulatory file quickly, to inquire into the strength of the patents contained in the 52-page data package, to determine whether there was European patent protection, to have the specialists at the Schering-Plough Research Institute do a preliminary safety analysis, or even simply to ask Upsher whether the FDA had raised any regulatory hurdles.[91] There is no reason why the materials submitted by Upsher could not have been circulated both to Audibert and to technical, scientific, regulatory, and patent professionals for an initial, even if hurried, review.

We recognize that significant time constraints may often require a very compressed review of potential products that

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[90] We recognize that the parties wanted to settle the case before the trial commenced, although it is not clear why this was an essential pre-condition for settlement. Many cases settle in the course of a trial.

[91] There were regulatory hurdles. The FDA had raised issues about Niacor-SR's dosing regimen and the need for a pharmacokinetic test. Niacor-SR was to "be labeled to take with meals," CX 917 at 107435, contrary to the assumption in materials provided to Audibert that it would be once-a-night dosing. Upsher had been having trouble for some time developing the pharmacokinetic test, which profiles the rate and extent of absorption of a drug in the body (Audibert, Tr. 4181). That test's validation method was not completed until November 4, 1998. Halvorsen, Tr. 3943-44; SPX 333 at 165879.

would fall far short of the formal due diligence that a company would otherwise conduct, given adequate time. Schering's failure to conduct formal due diligence does not, in itself, mandate a conclusion that the side deal for Upsher licenses was a pretext to mask the payment of substantial consideration for a deferred entry date.[92] However, Schering's minimal analysis of the Niacor-SR opportunity must be weighed heavily, along with the other facts in this case, as we determine whether Schering paid $60 million for licenses or for delay.

D. Inferences Derived from Conduct After the Settlement

The Initial Decision concluded that there was "substantial, reliable evidence to explain Respondents' post-deal conduct and attendant decisions not to pursue Niacor-SR." ID at 109. This conclusion, however, is based more on a quantitative count of individual communications between Schering and Upsher than on their substance. (IDF 263-66, 271-74, 279, 280, 282, 284, and 287-89 review the post-agreement communications between the parties from June 24, 1997 to September 24, 1998.)[93] A closer examination of the content and context of these communications reveals that most of them concerned matters necessary to initiate a relationship between the parties – such as confidentiality agreements and proposed amendments to the Settlement Agreement – rather than

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[92] We reject any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table when such a review concludes. We therefore do not rely on Dr. Levy's opinion about the acceptable parameters of due diligence. However, our own findings show there was ample record evidence to support a conclusion that Schering's analysis of the Niacor-SR opportunity was perfunctory.

[93] In addition to written communications, there were also some, but few, conversations between Schering and Upsher employees. IDF 316 records at least two meetings and 21 other documented communications between Schering and Upsher in 1997 after the licensing agreement, as well as some telephone calls.

substantive matters. In fact, the parties did not communicate at all about substantive issues as important as Upsher's decision to put development of Niacor-SR on hold and its later decision to terminate Niacor-SR development altogether – decisions that essentially suspended and then wiped out the benefits that were ostensible consideration for Schering's $60 million payment.

In fact, there were virtually no substantive communications about Niacor-SR, the key licensed product. For example, IDF 282 notes that "[d]uring 1998, Upsher remained in contact with Schering-Plough regarding the licensed products" and cites four documents: CX 1088, CX 1111, SPX 251, and USX 665. CX 1088 was an aggregate of other documents; the only document included in this aggregate dated after 1997 was a copy of Upsher's October 6, 1998 letter (CX 1111) announcing the termination of its work on Niacor-SR. The other two cited documents are a January 1998 draft of the Manufacturing Agreement (USX 665) and an April 1998 letter from Ray Kapur's secretary (SPX 251) enclosing signed confidentiality agreements, a preliminary step in the relationship that took 10 months to complete after the Agreement was signed.

Many of the communications that did take place concerned tasks that were never accomplished. For example, Schering and Upsher exchanged correspondence and drafts relating to a Manufacturing Agreement that concerned such issues as the supply and delivery of the licensed products. SPX 255; Kralovec, Tr. 5050-55; USX 732; SPX 217; SPX 251 (Jan. 1998). The proposed Manufacturing Agreement was dropped, and there was no further correspondence on the subject after January 1998. USX 665.

The few requests that Schering did make for information about Niacor-SR went unfulfilled, and Schering did not continue to request the information. For example, in response to a Schering request for information on Niacor-SR, Troup agreed that Upsher would send Schering the Niacor-SR registration information in segments so that Schering would not

have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) was completed. IDF 265; SPX 10; SPX 12 at SP 05 00013; Audibert, Tr. 4156. However, Audibert received only the protocols, and did not renew his request for information on Niacor-SR thereafter. Audibert, Tr. 4142, 4149-50, 4154-57, 4360; SPX 251.

There is virtually no correspondence about the key question in which Schering had such a substantial stake: the progress of Niacor-SR's development and the NDA. From November 12, 1997, to September 24, 1998 – when Upsher disclosed that it was no longer developing Niacor-SR – Schering and Upsher exchanged a total of two communications even though Upsher was to have submitted the NDA for Niacor-SR to the FDA in October 1997. USX 665; SPX 251. Of these two communications, only one arguably touched upon the status of Niacor-SR – an April 20, 1998 letter from the secretary of Ray Kapur, the head of Schering's Warrick generic division. SPX 251.[94] In a cover letter, Desiree Malanga enclosed executed confidentiality agreements, asked for a status report on the generic Pentoxifylline dossier, and then asked "in addition" that Upsher provide "complete information" on Niacor-SR to Thomas Lauda. SPX 251. This request for information on Niacor-SR was not honored, and Schering did not follow up. Audibert, Tr. 4156-57, 4360.[95]

The Initial Decision's findings highlight the impact of the disappointing sales of Kos's Niaspan on the parties' decisions about Niacor-SR. IDF 275-81. IDF 275 states that Kos's sales were below what "everyone" had expected. Neither Schering nor Searle had adopted the analysts' inflated projections for Niaspan. CX 558; Egan, Tr. 7913. Moreover, the Initial Decision ignores the clear evidence that in August 1997, well

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[94] The other communication was a January 12, 1998 draft of the never-finalized proposed Manufacturing Agreement. USX 665.

[95] Halvorsen testified that Upsher did provide some information on Pentoxifylline in response to this request. Halvorsen, Tr. 3980-82.

before Niaspan's sales were announced in November, Upsher was considering the abandonment of Niacor-SR (CX 1357) – primarily because of Niaspan's superior clinical profile and earlier entry. See, e.g., CX 930 at USL 13192; CX 963 at 12583, 12581; CX 1357. When Upsher explained its reasons for terminating the development of Niacor-SR to Schering in 1998 (CX 1111), Kos's sales were a secondary reason for dropping the program.

In addition to significant errors of omission, the Initial Decision relies heavily on unreliable evidence and ignores other evidence that is more reliable. For example, the findings in the Initial Decision that deal with Upsher's termination of Niacor-SR place great weight on the self-serving, after-the-fact testimony of individuals like Audibert, Troup, and Lauda, which emphasizes the impact of Niaspan sales. The findings ignore contemporaneous business documents, which make it clear that disappointing sales were a subsidiary consideration. We believe that the documents are more credible.

Because of these errors and omissions in the Initial Decision, the Commission substitutes the following findings for IDF 262-89:

1. Findings of Fact on the Post-Settlement Conduct of Schering and Upsher

On July 2, 1997, eight days after Schering's Board of Directors approved the Niacor-SR license on June 24, 1997 (CX 340), Kapur informed Cesan that Global Marketing would take responsibility for Niacor-SR, while Warrick, Schering's subsidiary, would oversee development of the generic products licensed from Uphser.[96] SPX 8. At the same time, Kapur

[96] Schering's United Kingdom subsidiary declined the Niacor-SR opportunity and informed Upsher's consultant that the opportunity had been passed on to Schering's International Division, which to that date had not responded. CX 1363.

notified Lauda that the Niacor-SR deal had been approved and that Global Marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. SPX 7; Lauda, Tr. 4349-50. James Audibert, the Global Marketing division employee whom Schering selected as designated project leader for Niacor-SR, testified at trial that he had been appointed to coordinate the preparation of the dossier for international filing. Audibert, Tr. 4140. Audibert testified in his investigative hearing, however, that he did not know what a "designated project leader" was for Niacor-SR, that he was not sure there was one, and finally that he assumed he was it de factc. CX 1483 at 123-24 (Audibert IH). He did not recall that Global Marketing had been assigned responsibility for registration of Niacor-SR in Europe; this assignment confused him because "global marketing is not responsible for registering products." SPX 7; SPX 8; CX 1483 at 121-23 (Audibert IH). He did not believe that he was responsible for development and registration work for Niacor-SR, and did not work on it. CX 1484 at 1670-71 (Audibert Dep.); CX 1483 at 124-25, 127 (Audibert IH).

After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. Troup, Tr. 5481-83. By the end of July, Upsher and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher. USX 732. As of the summer of 1997, Upsher was going forward with its NDA for Niacor-SR and Upsher's primary activity was to complete the final study reports and the ISS/ISE. Halvorsen, Tr. 3975. The patient phases of all four clinical studies had concluded before June 1997 and Upsher was in the process of compiling the data. Halvorsen, Tr. 3912. These agreements, as well as the ISS/ISE, were never completed.

During June and July 1997, Upsher was working on its Niacor-SR package insert to include with its NDA submission. Freese, Tr. 4990; USX 308. By July 21, 1997, Upsher had developed a revised draft of its package insert. Freese, Tr. 4990; USX 308. Upsher's draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. Freese, Tr. 4990; USX 308 at 110477-9. The package insert was never shown to Schering.

Before August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data (in the first of several communications between the two representatives). Halvorsen, Tr. 3976-77; USX 189. During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher had conducted with Niacor-SR for FDA approval – the two pivotal studies and the two follow-on studies. Halvorsen, Tr. 3976-77; USX 189. On August 14, 1997, Audibert sent Halvorsen a fax to arrange a meeting at Upsher for the week of September 15. USX 189. That meeting never took place.

Halvorsen testified that in August 1997, Upsher was still planning to file its NDA for approval of Niacor-SR at the end of 1997. Halvorsen, Tr. 3977-78. Halvorsen told Audibert that he did not believe that clinical data would be available until late October, and that what Upsher would have at that time were the final reports from the individual studies, and not the ISS/ISE. CX 780 at 00236. Schering was not told that Upsher was simultaneously considering the abandonment of all work on the Niacor-SR NDA in light of the approval of Kos's Niaspan on July 28, 1997. An August 12, 1997 Upsher memorandum "review[ed] recent changes in the marketplace that may significantly impact the potential marketability of the Niacor SR product." CX 1357 (emphasis in original). Kos's product would use once-a-night dosing to minimize flushing, while Niacor-SR was to have twice-a-day dosing. Id. According to the memorandum, "It appears that Niacor SR will have a

similar clinical profile versus Niaspan as it relates to the reduction of LDL, however Niaspan has a decided advantage on the reduction of Triglycerides, and the increase of HDL. Niacor SR also seems to [. . . affect] Lipoprotein more significantly than Niaspan." CX 1357 at 11931 (emphasis in original). Niacor-SR "will be a late entry into the Lipid Management category. Based on the information at hand it would seem that the product would also be inferior to the Niaspan product. Approval of the present form of Niacor SR is not eminent [sic] and may face delays." Id. at 11932 (emphasis in original).[97] Upsher did not terminate the program at that point, but did decide in October to devote "minimal activity" to the Niacor-SR NDA. CX 963 at 12579-81.

In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States. Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480. The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos's stock price, which had peaked around $44 per share, plummeted to $5 per share.[98] Troup, Tr. 5480. By that time, however, Upsher had already decided to devote only "minimal

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[97] Halvorsen testified at trial that the August 12, 1997 memorandum mistakenly indicated that Upsher would "need to conduct further studies to enable Niacor SR to be marketed with indications similar to Niaspan," at additional cost and delay. Halvorsen, Tr. 3950-52, 3957-60; CX 1357 at 11932. As it turns out, Upsher found out after August 1997 that the FDA had suggested those indications on the basis of general experience with niacin, not on any "outcome studies" conducted by Kos. Halvorsen, Tr. 3950-52. Ironically, Schering was aware that these additional indications for Kos's Niaspan product had been suggested by the FDA. SPX 22 at 2746. Upsher did not contact Schering to clarify Upsher's mistaken impression, nor did Upsher attempt to clarify this question with the FDA. Regardless, Upsher's struggles with development of the pharmacokinetic test validation method and completion of the ISS/ISE show that the memorandum was prescient when it concluded that Niacor-SR approval was not imminent.

[98] Schering had not shared the analysts' overly simplistic projections for Niaspan sales, nor had Searle. SPX 47; Egan, Tr. 7913-14.

activity" to Niacor-SR, primarily because of Niaspan's superior clinical profile, additional indications, and earlier entry. See, e.g., CX 930 at USL 13192; CX 963 at 12579-81; CX 1357. Upsher's letter to Schering, stating its reasons for terminating the development of Niacor-SR, makes clear that Kos's sales were a secondary reason for dropping the program. See CX 1111 (Kralovec writes that the Kos sales results "reinforced" the decision).

According to Troup, an unidentified person at Schering informed Upsher in March 1998 that Schering was no longer interested in marketing Niacor-SR outside the U.S. Although Halvorsen and Troup both were present at the meeting where Upsher decided to discontinue further work and wrap up in an unfinished state the contract research that Upsher had begun with third-party research firms, neither recalled who at Schering called with this important information, or even who at Upsher received the communication. Halvorsen, Tr. 3925; Troup, Tr. 5608-09. The information was never confirmed in writing. As noted above, the parties exchanged only two written communications in all of 1998 before the termination. USX 665; SPX 251.

In September 1998, Troup, Audibert, and Kapur had a telephone conversation about the status of Niacor-SR. Audibert, Tr. 4158-59; CX 1088 at 006-7. Troup reported that Upsher was not planning to file its NDA for FDA approval. CX 1088 at SP 05 006-07; CX 1111. In this conversation, Troup explained that Niaspan appeared to be marginally better than Niacor-SR. CX 1088; CX 1111; see also SPX 15 at 00057 (Audibert's September 1997 memo to Lauda on this discussion). Upsher believed that because Niaspan had received indications (i.e., FDA approval) for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those same indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60.

Upsher also believed that Niaspan was superior in other ways, aside from the additional testing Upsher mistakenly believed Kos had performed. See, e.g., SPX 15 at 16 00057; CX 930 at USL 13192; CX 1097; CX 1357.

For its part, Schering discontinued efforts to bring Niacor-SR to market for several reasons. Audibert, Tr. 4144-45; Lauda, Tr. 4352. As set out in Audibert's memorandum, first, Upsher believed that "Niaspan is a marginally better product than Niacor-SR in terms of safety and efficacy." CX 1088 at 05 0006. Second, Audibert noted that "in August '98, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." SPX 15 at 16 00057. The fact that Upsher had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together an international dossier than had originally been anticipated. Audibert, Tr. 4145; SPX 15. Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. Audibert, Tr. 4145.

As Kapur had requested on October 6, 1998, Paul Kralovec, Upsher's Chief Financial Officer, provided written confirmation of Upsher's decision to suspend its efforts on Niacor-SR. CX 1111; Kralovec, Tr. 5057; Lauda, Tr. 4428-29. In the letter, which was also copied to Troup, Kralovec again confirmed the reasons for Upsher's decision not to proceed with U.S. approval. CX 1111. Kralovec's letter based that decision "first and foremost" on FDA's requirement that Upsher complete a pharmacokinetic study, with Kos's sales performance a secondary consideration. CX 1111.[99]

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[99] The memorandum stated three reasons for Upsher's decision to discontinue the NDA, last of which is Niaspan's sales: (1) Upsher was "focusing their efforts in defending their generic amiodarone against AHP,

Neither Troup in the September 1998 telephone call, nor Kralovec in his October 1998 written confirmation, mentioned to Schering the mysterious March conversation in which someone from Schering had supposedly stated that the company did not plan to market the product outside the U.S. SPX 15; CX 1111.

2. Factual Conclusions About Post-Settlement Conduct

The evidence from the post-settlement conduct, considered as a whole, demonstrates that Schering had little interest in Niacor-SR or any of the other licensed products. The lack of communication between Upsher and Schering about the development of Niacor-SR – especially during the fall of 1997, before Kos's disappointing sales were made public and after Upsher decided unilaterally to place only minimal effort into development activities – suggests that Upsher understood Schering was not particularly interested in the licensed products.[100] This conclusion is buttressed by the fact that Upsher simply ignored Schering's sporadic requests for information, and ultimately made a unilateral decision essentially to suspend its work, without eliciting even a mild protest from Schering. The post-settlement conduct only confirms the conclusion that Schering's payment of $60 million was not consideration for the licenses.

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(2) based on the clinical data, the profile of Niacor seems to be slightly inferior to Niaspan (Kos), and (3) the Kos product has not been successful in spite of Kos investing considerably more sales and promotional efforts than Upsher intended to do." SPX 15 at 1600057.

[100] Because the evidence shows that Schering had not shared the investment analysts' optimistic forecasts for Niaspan sales, the fact that Niaspan's sales were not as high as forecast fails to explain fully Schering's lackadaisical attitude.

E. Summary Factual Conclusions on the Valuation of the Upsher Licenses

There is a direct link between the payment by Schering for the Upsher licenses and Upsher's commitment not to enter before September 1, 2001. Schering's payments were neither keyed to any milestones in the development of the licensed products nor dependent on any obligations of Upsher to cooperate with Schering. At every negotiating session, Upsher's senior representative demanded compensation in return for an agreement not to enter. Some Schering representatives were concerned about the antitrust consequences of an outright payment to Upsher for delay, but Schering's senior management believed these obstacles could be surmounted if the payments for the Upsher licenses were justified on a stand-alone basis.

As a practical matter, the only Upsher license that Schering attempted to value related to a niacin-based product, Niacor-SR. A number of people in Schering were familiar with niacin-based products, as the result of a recently terminated negotiation involving a different niacin-based product made by another company, Kos Pharmaceuticals. These people had serious reservations about the commercial potential of such products. For reasons that the parties have not explained, none of these knowledgeable people was included in the negotiations of the final price that ostensibly would be paid for a license to Niacor-SR – nor were these knowledgeable people consulted when a single Schering employee made the "forecast" of Niacor-SR's sales and profit potential that was the basis for approval by the Schering Board.

This "forecast" was little more than a simple mathematical exercise. Even if we assume that there were serious time pressures, obvious questions were not even asked, nor were they pursued after the agreement was signed. It is not credible that Schering would have been satisfied with such a cursory

examination, if management really was concerned about the value of the Upsher licenses. The post-settlement conduct of the parties reinforces these conclusions. The record demonstrates that Schering did not evidence any significant interest in the licensed products once the settlement had been concluded and, ultimately, all development was terminated. In the end, the Upsher licenses were worth nothing to Schering.

On the basis of the record as a whole, we find that there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses. We therefore conclude that Schering did in fact pay Upsher for delayed entry, which, in the circumstances of this case, was an agreement that unreasonably restrains commerce.

V. The Agreement Between Schering and AHP

The complaint in this case also challenges the legality of a litigation settlement between Schering and AHP, which was concluded in June 1998 – approximately one year after the Schering/Upsher settlement. AHP agreed to a consent order based on this transaction, but Schering has continued to defend it, and the Initial Decision upheld Schering's position. Complaint Counsel appeals from this dismissal as well.

There is far less record evidence about the Schering/AHP agreement than there is about the Schering/Upsher agreement, but our analysis will proceed along the same path, highlighting the similarities and the differences between the two agreements to the extent applicable. We will examine the core elements of Complaint Counsel's case, consider whether it is necessary to address the merits of the underlying patent dispute and, finally,

evaluate the ancillarity defense.[101] Based on our analysis of the record, we reverse the Initial Decision and conclude that the Schering/AHP settlement was an unreasonable agreement in violation of Section 5 of the FTC Act.

A. The Evidence in Support of Complaint Counsel's Case

The Schering/AHP agreement delayed entry of the generic product to be offered by the ESI subsidiary of AHP until January 1, 2004.[102] We obviously have no evidence on the actual market impact of ESI's generic product, but we do have evidence of predicted effects similar to the predictive evidence available for Upsher's product. [redacted from public record version] [redacted from public record version .][103] In addition, the economic studies cited above found that generic prices fall further as the number of generic producers increases. See Richard G. Frank & David S. Salkever, Generic Entry and the Price of Pharmaceuticals, 6 J. Econ. & Mgmt. Strategy 75, 83 (1997) ("expanded entry is consistent with a downward drift in the ratio of generic to brand-name price"); Richard E. Caves, et al., Patent Expiration, Entry, and Competition in the U.S.

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[101] There also was a side agreement in this settlement that provided for a payment of $15 million by Schering to AHP's ESI unit, in return for certain licenses. However, Schering has conceded that it agreed to pay another $5 million (for "legal fees") simply to induce AHP to settle the case, and it later agreed to pay $10 million more contingent on FDA approval of ESI's generic version of K-Dur – not the other products ESI licensed to Schering. (IDF 370-75; Schering Ans. Br. at 50.) FDA approval was obtained and the additional $10 million were paid. The total payment was thus $30 million. In these circumstances, we do not believe it is necessary to explore whether the ESI licenses were worth the $15 million ascribed to them in the settlement.

[102] The Commission's April 2002 settlement with AHP did not mandate an earlier entry date.

[103] [redacted from public record version]

Pharmaceutical Industry, Brookings Papers on Economic Activity: Microeconomics 1, 34-38 (1991); Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, July 1998.

The record does not contain similar predictions from the files of Schering, but we have no evidence from which we could conclude that the impact of ESI's generic would be qualitatively different from the impact of Upsher's generic. Since these predictions are consistent with the record evidence about both the predicted and the actual impact of another generic on the sales of the same patented drug (see Part II.B., above), we see no reason to arrive at a different conclusion on the likely competitive effects of an agreement that delayed ESI's entry.

B. The Need to Address the Merits of the Underlying Patent Dispute

The patent dispute between Schering and AHP, like Schering's dispute with Upsher, involved issues of infringement as well as validity. Therefore, we cannot presume either that Schering had the right to exclude or that AHP had the right to enter. For the reasons set out in Part II.C., above, we believe it is neither necessary nor helpful to delve into the merits of the patent dispute.

C. The Ancillarity Defense

We have already weighed the evidence presented by Schering's expert witnesses on the general desirability of patent settlements and the possible efficiency justifications for payments by pioneers to generic manufacturers in some situations. We therefore believe it is appropriate to deal with this issue in the context of the Schering/AHP settlement in a

way that parallels the conclusions about the Schering/Upsher settlement. As discussed above, it is possible to envision special hypothetical cases where some payments from pioneers to generics could be efficient and beneficial to consumers. An argument that these payments facilitate and are ancillary to procompetitive settlements invokes an affirmative defense, however, and a respondent who relies on it also has the burden of demonstrating that the facts fit some special hypothetical.

A sum that ultimately amounted to $15 million was paid simply to get ESI's agreement on settlement terms that delayed generic entry until 2004. Of this amount, $5 million were ostensibly for "legal fees." This might not be an unreasonable nuisance settlement – it is probably well in excess of AHP's attorneys fees, but obviously Schering faced litigation expenses of its own. However, the additional $10 million, contingent on FDA approval of the generic product, are harder to justify. ESI was not a "cash starved" generic and there is no evidence that the payment would facilitate generic entry in force. Schering's claim is rather that ESI was adamant on the issue and that a settlement-minded judge put pressure on Schering to yield.[104]

We accept that Schering was subject to intense, and perhaps unseemly, judicial pressure to settle the patent litigation, and Schering may well have been concerned about its future litigation prospects if it resisted. In other words, the pressure could have adversely affected its perceived bargaining position. We are troubled, however, by the fact that Schering's only response to the pressure was to look for innovative ways to structure payments to AHP; the January 1, 2004 date for generic entry was apparently non-negotiable. There is no record evidence to explain why the entry date was non-negotiable from Schering's point of view or why an earlier date would have been an unsatisfactory substitute for cash from AHP's point of view. In other words, there is no explanation

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[104] Schering Ans. Br. at 50.

for the failure to even explore an obviously less restrictive alternative. As discussed above in another context,[105] the mere fact that a patent holder's bargaining position has been impaired does not justify the payment of money to a potential generic entrant.

As a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence, and our decision on this aspect of the case will have no impact on the scope of the order we enter.[106] However, Commission determinations serve to provide prospective guidance as well as retrospective evaluations, and we believe it is important to signal our disapproval of the way that Schering responded to judicial pressures. Accordingly, we find that conduct of this kind violates the law.

VI. The Monopolization Counts

In addition to counts that invoke the conspiracy provisions of Section 1 of the Sherman Act (Comp. ¶¶ 68, 69), the complaint also pleads two counts that invoke the monopolization provisions of Sherman Act Section 2 (Comp. ¶¶ 70, 71).[107] As discussed above, there is adequate evidence to support the conclusion that the agreements to defer competition between Schering's patented drug and its generic equivalents will cause significant consumer harm, under

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[105] See discussion in Part II.B.4, above, rejecting an argument that payments are justified simply because Hatch-Waxman has shifted the relative bargaining power of the parties.

[106] The Commission's Order settling the complaint with AHP is final. See Schering-Plough Corp., FTC Dkt. No. 9297, Consent Order as to American Home Products Corp. (Apr. 2, 2002), available at <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

[107] The counts plead a violation of Section 5 of the Federal Trade Commission Act, but the standards for applying Section 5 are, for the most part, co-extensive with the Sherman Act. See discussion in ABA Section of Antitrust Law, Antitrust Law Developments 607 (5th ed. 2002).

Section 1 standards. The Upsher and AHP agreements postponed availability of substantial quantities of lower-priced therapeutically equivalent drugs and thereby caused consumer injury that is readily identifiable (even if it may not be readily quantifiable). In light of our conclusions on the conspiracy counts, it is not necessary to rule on the additional monopolization counts – and there are also affirmative reasons for declining to do so.

The proof in this case focused on the legality of two contracts, the Schering/Upsher and the Schering/AHP settlement agreements. There is no claim that unilateral conduct by anyone violated the antitrust laws. Moreover, determination of liability on the monopolization counts of the complaint would not affect our views on the appropriate order in this case. We therefore do not believe it would be useful either to canvass the record to see whether there is adequate evidence to sustain these counts under the most commonly accepted standards for monopolization cases[108] or, alternatively, to consider whether the case should be remanded for further proceedings under the appropriate standards. Accordingly, we neither endorse nor reject the conclusions of the Initial Decision on these issues, but rather find that it is not appropriate for the Commission to address them at this time.

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[108] Reliance on direct evidence of market effects, rather than inferences from "market" shares, is a less familiar method of proof in a Section 2 monopolization context. See id. at 232 n.16 and cases cited ("Numerous cases have held specifically that proof of a relevant market is an essential element of any claim for monopolization or attempted monopolization under § 2."); but see PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 107-08 (2d Cir. 2002); Re/Max Int'l, Inc. v. Realty One, Inc., 173 F.3d 995, 1016 (6th Cir. 1999), cert denied, 535 U.S. 987 (2002).

VII. The Appeal from the Administrative Law Judge's Evidentiary Rulings

Complaint Counsel have also asked the Commission to vacate four rulings by the Administrative Law Judge that excluded certain rebuttal evidence. If we were to do so, of course, it would be necessary to remand the case and reopen the record to admit the evidence.[109] For the reasons outlined below, we do not believe it is necessary to take this step at this time.

The first ruling denied discovery requested by Complaint Counsel, in order to rebut a claim that capacity constraints would have prevented Upsher from bringing its generic product to market before the agreed-on date of September 1, 2001. Since we find that Upsher's evidence on this point is insufficient, even without the rebuttal evidence, we decline to overturn the ruling on this issue.[110]

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[109] The courts and the Commission apply an "abuse of discretion" standard when reviewing claims of error in evidentiary rulings at the trial or initial hearing level. See General Elec. Co. v. Joiner, 522 U.S. 136, 141 (1997), and cases cited therein; Missouri Portland Cement Co., 77 F.T.C. 1643 (1970). While this standard means that the Commission will not routinely disturb the ALJ's denial of discovery or exclusion of evidence, the Commission may reverse a procedural decision and reopen the record, as necessary or appropriate, where the ALJ's ruling is found to be "unduly restrictive" or otherwise prejudicial or improper. See, e.g., Foster-Milburn Co., 51 F.T.C. 369, 371 (1954) (hearing examiner improperly denied complaint counsel's request to present scientific rebuttal witnesses); see also Commission Rule 3.54, 16 C.F.R. § 3.54 (reserving the Commission's discretion to exercise all of the powers it could have exercised if it had made the initial decision and, if it believes it should have additional information or views of the parties bearing upon the order to be issued, to withhold final action pending the receipt of such information or views).

[110] This does not mean that we agree with the ruling on the merits. If Complaint Counsel's chronological account is accurate, and if the evidence had been material, it seems that there could have been prejudice from a six-week delay in the resolution of the "emergency motion" in aid of discovery. See App. Br. at 78-81.

The second ruling excluded rebuttal testimony by witness Bresnahan on the substitutability of other potassium products for Schering's K-Dur 20. We have found that evidence of this kind is not material for a decision in this case, whatever relevance it might have for market definition in another kind of case. Accordingly, we decline to overturn the ruling.

The third ruling excluded certain rebuttal testimony by witness Max Bazerman on risk aversion because his underlying expert report was not filed in time. The excluded testimony apparently took issue with testimony of Schering's experts that Schering was risk averse in settlement negotiations with Upsher and AHP (and, hence, presumably willing to place a high value on settlement). We do not believe that the level of Schering's risk aversion is relevant to our decision in this case.

The extent to which parties are risk averse may affect how they are willing to compromise the entry date when settling patent litigation. However, we do not challenge agreements on entry dates, standing alone. The issue in this case is whether payments from pioneer to generic have distorted the calculus that would otherwise obtain – based on whatever risk preferences the parties might have – and our opinion does not depend on testimony about relative risk preferences. Accordingly, the ruling is harmless and will not be disturbed.[111]

The fourth ruling excluded rebuttal testimony of a witness from Walgreens, again on the substitution of other products for K-Dur 20. The rejected testimony related to a market definition issue that is essentially the same as the issue involved in the second ruling, and we decline to overturn it for the same reasons.

We can revisit each of these rulings in the event that further proceedings in this case make it necessary to do so.

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[111] We again note, however, that the ruling could have been unduly prejudicial if Complaint Counsel's chronology is accurate and the evidence had been material for our decision. See App. Br. at 85-88.

VIII. Conclusion

For all of the reasons outlined above, we conclude that both the Schering/Upsher and the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. Specifically, we reverse the Initial Decision and find that the charges in the complaint that are grounded in Section 1 of the Sherman Act (Paragraphs 68-69) have been proven. We neither affirm nor reverse the Initial Decision with respect to those charges in the complaint that are grounded in Section 2 of the Sherman Act (Paragraphs 70-71).

Although we find that these two settlement agreements violated Section 5, after an appropriately structured rule-of-reason inquiry, we also note that the agreements in question were consummated well before the Commission launched the investigations that resulted ultimately in complaints and consent orders in comparable situations.[112] Although counsel for Schering, at least, were aware of the particular problems posed by reverse payments and attempted (unsuccessfully) to avoid them, we do not believe that these problems were as obvious in 1997 and 1998 as they are today. Our own view of these matters has been informed by what we have learned about pioneer/generic settlements since that time. For these reasons, we have crafted an order that is appropriate in the circumstances.

The order provides for prospective relief only.[113] We have found that the agreements were unreasonable restraints of trade because they were likely to cause consumer harm that outweighed any associated pro-consumer efficiencies. We also

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[112] See cases cited in note 3, supra.

[113] It may be appropriate in the future to seek retroactive relief, like disgorgement or redress, in comparable situations. See FTC Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820 (Aug. 4, 2003), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,231, available at <http://www.ftc.gov/os/2003/07/disgorgementfrn.htm>.

have found that the reverse payments did, in fact, cause delay and that this delay resulted in substantial consumer harm. We have not, however, attempted to quantify the net harm to consumers and express no opinion on what it might be.

The order is modeled on Complaint Counsel's proposed remedy, with one significant exception. We delete in their entirety proposed provisions relating to a first-filing generic's 180-day exclusivity. We have not analyzed the effects of any such agreements in this opinion and believe it is inappropriate to address them in the order.

Paragraph II of the order deals with final settlements of patent litigation. It prohibits settlements under which the generic "receives anything of value" and agrees to defer its own research and development, production or sales activities. Consistent with prior consent orders, there is a specific exception for payments to the generic that are linked to litigation costs, up to $2 million, and for which the Commission has been notified of the settlement.

Paragraph III of the order prohibits settlement agreements that restrict the generic's activities with respect to drug products that are subject to neither a pending claim of patent infringement nor a likely future claim. This provision is consistent with an extensive body of case law that prohibits restrictions on activities outside the scope of a patent claim.[114]

Paragraph IV of the order deals with interim settlements of pioneer/generic patent litigation. The substantive prohibition against providing "anything of value" to the generic is subject to a broad exception for agreements that are affirmatively sanctioned by a court order after notification to the

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[114] The basic reason is that, in the absence of a patent blockade, the arrangement "harms competition among actual or likely potential competitors . . ." U.S. Dep't of Justice & Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (1995) § 3.1, reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132, available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>.

Commission and full opportunity by the Commission to participate in the proceeding.

Paragraph V of the order specifies the form of notifications to the Commission that may be required, and the remaining paragraphs provide for the usual compliance reports and visitation rights. The order expires in 10 years.

We finally would like to express our appreciation to all counsel for their extensive and thoughtful submissions that have helped us to resolve this complex matter.

APPENDIX

Witnesses and People Referenced in Opinion

Sumanth Addanki, Economic Expert (Schering expert witness)
James Audibert, Schering-Plough, Senior Director of Commercial Optimization
Daniel Bell, Kos Pharmaceuticals, President and Chief Executive Officer
Timothy F. Bresnahan, Economic Expert (Complaint Counsel expert witness)
Nicholas Cannella, Upsher-Smith, Legal Counsel
Raul Cesan, Schering-Plough, President of Pharmaceuticals Worldwide
Toni DeMola, Schering-Plough, Member Cardiovascular Licensing Group
Michael Dey, ESI Lederle, Chief Executive Officer
Denise Dolan, Upsher-Smith, Marketing Official
Martin Driscoll, Schering-Plough, Vice-President of Sales and Marketing, Key Pharmaceuticals (Key marketed K-Dur 20)
James Egan, Searle, Formerly, Senior Director of Licensing and Business Development
Lori Freese, Upsher-Smith, Manager of Professional Services
James Furniss, European Pharmaceutical Expert (Schering Expert Witness)
Karin Gast, Schering-Plough, Director of Business Development
Dean Goldberg, United Healthcare, Pharmaceutical Expert (Complaint Counsel expert witness)
David Grewcock, Schering-Plough, Member Cardiovascular Licensing Group
Marc Halvorsen, Upsher-Smith, Director of Clinical and Regulatory Affairs
Andrew Hirschberg, Upsher-Smith, Consultant
John Hoffman, Schering-Plough, Associate General Counsel

Zola Horovitz, Pharmaceutical Expert (Schering expert witness)

Raman Kapur, Schering-Plough, President, Warrick Pharmaceuticals (Schering-Plough's generic drug affiliate)

William Kerr, Economic Expert (Schering expert witness)

Paul Kralovec, Upsher-Smith, Chief Financial Officer

Thomas Lauda, Schering-Plough, Executive Vice President of Global Marketing

Nelson Levy, Licensing Expert (Complaint Counsel expert witness)

Vicki O'Neil, Upsher-Smith, Business Development Official

Mukesh Patel, Kos Pharmaceuticals, Licensing and Business Development

Charles (Rick) Rule, Antitrust Expert (Upsher-Smith Witness)

Raymond Russo, Schering-Plough, Marketing Director, Key Pharmaceuticals

Russell Teagarden, Merck-Medco, Pharmaceutical Pricing Expert (Complaint Counsel expert witness)

Paul Thompson, Schering-Plough, Licensing Attorney involved with Upsher-Smith transaction

Ian Troup, Upsher-Smith, President and Chief Operating Officer

Jeffrey Wasserstein, Schering-Plough, Vice President of Business Development

Robert Willig, Economic Expert (Schering expert witness)

Richard Zahn, Schering-Plough, Executive who supervised Driscoll

APPENDIX C

INITIAL DECISION FILED:
JUNE 27, 2002

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,
A CORPORATION,

UPSHER-SMITH LABORATORIES,
A CORPORATION,

AND

AMERICAN HOME PRODUCTS CORPORATION,
A CORPORATION.

PUBLIC RECORD VERSION
DOCKET NO. 9297

INITIAL DECISION

By: D. Michael Chappell, Administrative Law Judge

Karen Bokat, Esq., Philip M. Eisenstat, Esq., Michael B. Kades, Esq., Judith Moreland, Esq., Seth C. Silber, Esq., Bradley S. Albert, Esq., Markus H. Meier, Esq., and Elizabeth R. Hilder, Esq.
Federal Trade Commission
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White & Case LLP
Counsel for Upsher-Smith Laboratories, Inc.

I. INTRODUCTION

A. Federal Trade Commission Complaint

The Federal Trade Commission issued its Complaint in this matter on March 30, 2001. The Complaint charges that Respondents Schering-Plough Corporation (Schering), Upsher-Smith Laboratories, Inc. (Upsher-Smith), and American Home Products Corporation (AHP) engaged in conduct that violates Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Complaint alleges that Respondents entered into unlawful agreements to delay entry of low-cost generic competition to Schering's prescription drug K-Dur 20. Before detailing the findings of fact and conclusions of law, the following overview is provided.

Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 and K-Dur 10, both of which are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which expires on September 5, 2006. On August 6, 1995, Upsher-Smith filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith submitted a

certification to the FDA, known as a Paragraph IV Certification, with this ANDA certifying that its product, Klor Con M20, did not infringe Schering's K-Dur 20 and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA.

Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor Con M20 infringed Schering's '743 patent. On June 17, 1997, Schering and Upsher-Smith agreed to settle their patent litigation. The Complaint alleges that through this settlement agreement, Schering agreed to make unconditional payments of $60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products. Complaint at ¶ 44.

On December 29, 1995, ESI Lederle, Incorporated ("ESI"), a division of AHP, submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. The Complaint alleges that Schering and AHP reached an agreement in principle settling their litigation in January 1998, and they executed a final settlement agreement on June 19, 1998. Complaint at ¶ 54. AHP agreed that its ESI division would not market any generic version of Schering's K-Dur 20 until January 2004, would not market more than one generic version of Schering's K-Dur 20 between January 2004 and

September 2006, and would not support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006. Complaint at ¶ 55. AHP received a payment from Schering of $5 million, and an additional payment of $10 million when its generic product received FDA approval in 1999. Complaint at ¶ 55.

The Complaint alleges that the agreements between Schering and Upsher-Smith, and between Schering and AHP, were agreements not to compete that unreasonably restrained commerce in violation of Section 5 of the FTC Act. Complaint at ¶¶ 68, 69.

The Complaint further alleges that Schering had monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and engaged in conduct intended to unlawfully preserve that monopoly power, in violation of Section 5 of the FTC Act. Complaint at ¶ 70. And, the Complaint alleges that Schering conspired separately with Upsher-Smith and with AHP to monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, in violation of Section 5 of the FTC Act. Complaint at ¶ 71.

B. Respondents' Answers

In answers filed April 23, 2001, Schering, Upsher-Smith and AHP denied that the agreements were unlawful, and offered a number of affirmative defenses. Upsher-Smith's answer asserted that its patent settlement agreement with Schering was lawful, reasonable, procompetitive and in the public interest.

In its answer, Schering asserted that its settlement agreement with Upsher-Smith allowed Upsher-Smith to bring its product to market in September 2001, five years before patent expiration. Schering asserted its settlement agreement

with ESI was forged under active judicial supervision and allowed ESI to bring its potassium chloride product to market over two years before Schering's patent expired. Schering further asserted that the Complaint fails to acknowledge that Schering has a valid patent giving it a right to exclude infringing products, the Complaint fails to allege that the procompetitive efficiencies of the settlement do not outweigh any actual or potential anticompetitive effects, and that the relief sought by the Complaint is contrary to public policy because it interferes with settlement of patent infringement litigation.

C. Procedural History

On October 12, 2001, the Complaint against AHP was withdrawn from adjudication for the Commission to consider a proposed consent agreement. The Commission approved the final consent order on April 2, 2002. Although AHP is no longer a party to the case, the legality of the Schering/AHP agreement remains at issue with respect to Schering.

Trial commenced on January 23, 2002 and ended on March 28, 2002, covering 8629 pages of transcript, with 41 witnesses testifying, and thousands of exhibits admitted into evidence. Closing arguments were heard on May 1, 2002.

On February 12, 2002, Upsher-Smith moved to dismiss the Complaint due to Complaint Counsel's failure to establish a prima facie case. Pursuant to Commission Rule 3.22(e), the ruling on the motion to dismiss was deferred until all evidence was received. In a ruling from the bench on March 22, 2002, Upsher-Smith's motion was denied on the grounds that the evidence presented created factual issues of dispute sufficient to defeat the motion to dismiss.

On March 6, 2002, the parties filed a joint motion to extend the deadline for filing the initial decision. By Order dated March 14, 2002, extraordinary circumstances were found to

exist sufficient to extend the deadline for filing the Initial Decision by 60 days until May 31, 2002. The record was closed on March 28, 2002. By Order dated May 29, 2002, continuing extraordinary circumstances were found to exist and the deadline was extended an additional 60 days. This initial decision is filed within 90 days of the close of the record.

D. Evidence

The Initial Decision is based on the transcript of the testimony, the exhibits properly admitted in evidence, and proposed findings of fact and conclusions of law and replies thereto filed by the parties. Numerous exhibits were conditionally admitted. Evidence, including transcripts from investigational hearings, which was conditionally admitted, was considered even though Complaint Counsel failed to properly connect up the evidence against all parties, and was found not to be dispositive to the determination of any material issue in the case.

The parties submitted extensive post-trial briefs and reply briefs. The Initial Decision contains only the material issues of fact and law. Proposed findings of facts not included in the Initial Decision were rejected either because they were not supported by the evidence or because they were not dispositive to the determination of the allegations of the Complaint.

Many of the documents and testimony were received into the record in camera. Where an entire document was given in camera treatment, but the portion of the document relied upon in this Initial Decision does not rise to the level necessary for in camera treatment, such information is disclosed in the public version of this Initial Decision, pursuant to 16 C.F.R. § 3.45(a) (the ALJ may disclose such in camera material to the extent necessary for the proper disposition of the proceeding).

E. Summary

Based upon the theories advanced by Complaint Counsel, for Complaint Counsel to prove that the agreements to settle the patent litigation between Schering and Upsher-Smith and between Schering and ESI were anticompetitive requires a presumption that the '743 patent was not valid or that Upsher-Smith's and ESI's products did not infringe the '743 patent. There is no basis in law or fact to make that presumption. In addition, Complaint Counsel has failed to meet its burden of proving the relevant product market or that Schering maintained an illegal monopoly within that market. Despite the emotional appeal which may exist for Complaint Counsel's position, an initial decision must be based on substantial, reliable evidence and well reasoned legal analysis. For the reasons set forth below, the violations alleged in the Complaint have not been proven and the Complaint will be dismissed.

II. FINDINGS OF FACT

A. Respondents

1. Schering-Plough Corporation

1. Schering-Plough Corporation ("Schering") is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. (Schering Answer at ¶ 3; CX 174 at FTC 0022249-50 (Schering 12/31/99 Form 10K)).

2. Key Pharmaceuticals, Inc. ("Key"), a Florida corporation, is a subsidiary of Schering. (CX 174 at FTC 0022315). It produces K-Dur 20, a 20 milliequivalent potassium chloride supplement, and holds the patent on that

product. Schering Answer at ¶ 34. Warrick Pharmaceuticals Corporation ("Warrick"), a Delaware corporation, is a subsidiary of Schering. CX 174 at FTC 0022318. It produces generic pharmaceutical products, and in some situations, produces generic versions of Schering's patented products once another generic has entered the market. (Russo, Tr. 3429-30).

3. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (Schering Answer at ¶ 7).

4. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S. C. § 44. (Schering Answer at ¶ 8).

2. Upsher-Smith Laboratories, Inc.

5. Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a business corporation organized under the laws of the state of Minnesota that has issued shares of common stock. (CX 1 (Upsher-Smith Articles of Incorporation); Upsher-Smith First Admissions, Nos. 1, 2. Its principal place of business is Plymouth, Minnesota. (Troup, Tr. 5397). Upsher-Smith is a privately-held company. (Tro[illegible], Tr.5398).

6. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Upsher-Smith manufactures pharmaceutical products at its facilities in Minnesota and ships products to the other 49 states of the United States. It purchases pharmaceutical ingredients for its pharmaceutical products from suppliers located outside Minnesota, and transfers funds across state lines in exchange for those ingredients. Upsher-Smith First Admissions, Nos. 12, 13, 14, 15, 16, 17, 18, 19, 20 and 21.

8. Upsher-Smith markets its products to retail, chain, and hospital pharmacies, and to key physician groups, primarily by means of wholesale and drug chain distribution channels throughout the United States. (CX 317 at USL 01643 (Upsher-Smith Financial Statements, 1/3/99 and 1/4/98)).

9. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. American Home Products Corporation

10. American Home Products Corporation ("AHP") is a corporation organized and existing under the laws of Delaware, with its principal place of business at Five Giralda Farms, Madison, New Jersey. It engages in the discovery, development and marketing of brand name and generic drugs, as well as "over the counter" medications. AHP Answer at ¶ 5; CX 484 at 05 00052.

11. Wyeth-Ayerst Pharmaceuticals, Inc. ("Wyeth"), is a subsidiary of AHP. ESI Lederle, Inc. ("ESI"), is a business unit of Wyeth. ESI engages in research, manufacture and sale primarily of generic drugs. AHP Answer at ¶ 6.

12. On October 10, 2001, Complaint Counsel and counsel for AHP filed a Joint Motion to Withdraw Respondent American Home Products from Adjudication in order for the Commission to consider an executed proposed consent agreement. On October 12, 2001, the Commission issued an Order Withdrawing Matter from Adjudication as to Respondent American Home Products Corporation. The Commission approved the final consent order April 2, 2002.

B. The Pharmaceutical Industry

13. Newly developed prescription drugs are sometimes referred to as "pioneer" or "innovator" or "branded" drugs.

(Hoffman, Tr. 2206-07; Dritsas, Tr. 4621). Approval for an innovator drug is sought by filing a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). (Hoffman, Tr. 2207).

14. Newly developed prescription drugs are often protected by patents. (Hoffman, Tr. 2215). A patent is granted by the federal government to the patent holder giving the holder exclusive rights to make, use, vend and to import the subject matter covered by the patent claims. (Miller, Tr. 3310-11:2; O'Shaughnessy, Tr. 7064-65).

15. A generic drug contains the same active ingredient as the branded or innovator drug, but not necessarily the same inactive ingredients. (Hoffman, Tr. 2207; Levy, Tr. 2186). Approval for a generic drug may be sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. (Hoffman, Tr. 2209; Troup, Tr. 5403). The ANDA applicant must demonstrate, among other things, that the generic drug is bioequivalent to the brand-name drug that it references. (Hoffman, Tr. 2208; Troup, Tr. 5403).

16. When a brand-name prescription drug is protected by one or more patents, an ANDA applicant that intends to market its generic prescription product prior to the expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand-name drug or (2) the patents are invalid. (Hoffman, Tr. 2215-16; Troup, Tr. 5404). This is known as a "Paragraph IV Certification." (Hoffman, Tr. 2216; Troup, Tr. 5404).

17. A bioequivalent drug contains the same active ingredient as the reference drug and is absorbed into the bloodstream at the same rate and extent, and remains at certain levels for the same period of time as the reference drug. (Hoffman, Tr. 2208).

18. Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. (Hoffman, Tr. 2278).

19. Generic drugs can offer price competition to the branded drug. The generic enters the market at a lower price than that of the branded drug. (Teagarden, Tr. 210-11; Goldberg, Tr. 137-38; Dritsas, Tr. 4743, 4904-05).

20. The price of generic drugs falls even further as additional generic versions of the same branded drug enter the market. (Schering Answer at ¶ 17; Goldberg, Tr. 120-21; Rosenthal, Tr. 1543).

21. Sales of the branded product decrease after generic entry because generics are substituted for the branded product. (Rosenthal, Tr.1538; Bresnahan, Tr. 462-63).

22. In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. (Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at ¶ 18). A pharmacist cannot substitute a generic that is not AB-rated for a branded drug without the physician's approval. (Bresnahan, Tr. 491; Russo, Tr. 3468).

23. In some states, pharmacists are required to substitute an AB-rated generic unless the physician directs otherwise. (Bresnahan, Tr. 1178; Addanki, Tr. 5998).

24. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. (CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93).

C. Geographic Market

25. The geographic market is the United States. (F. 26-28).

26. Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose

products have been approved for sale in the United States by the FDA. (Hoffman, Tr. at 2206).

27. Schering has FDA approval to sell its K-Dur extended release potassium chloride tablets. (Kerr, Tr. 6561). Schering sells K-Dur throughout the United States. (CX 18 at SP 23 00044). Of the $290 million in K-Dur 20 sales in 2000, Schering made $287 million of those sales in the U.S., and $3 million worth internationally in 2000. (Audibert, Tr. 4212-13).

28. Upsher-Smith has FDA approval to sell its Klor-Con M extended release potassium chloride tablets. (CX 59; Hoffman, Tr. 2273-74). Since Upsher-Smith began Klor Con M20 in September 2001, Upsher-Smith has been shipping it to all the major wholesalers and chain distribution centers throughout the United States. (Kralovec, Tr. 5076-77). Upsher-Smith does not sell Klor-Con M20 outside of the United States. (Dritsas, Tr. 4620).

D. Relevant Product Market

29. The relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. (F. 31-118).

30. Professor Bresnahan incorrectly defined the relevant product market as K-Dur 20 mEq. (F. 31-118).

1. K-Dur 20 is one of many potassium chloride products on the market

31. K-Dur is a potassium chloride product marketed by Schering. (Russo, Tr. 3410-11). K-Dur is primarily used to treat potassium depletion in coronary artery disease patients. (Russo, Tr. 3410-11). To treat a patient's coronary artery disease, physicians often prescribe products that are also diuretics, causing a depletion in potassium, referred to as hypokalemia. (Russo, Tr. 3410- 11; Goldberg, Tr. 125-26).

32. K-Dur is marketed in 10 mEq and 20 mEq dosage strengths. (Russo, Tr. 3411). The 10 mEq and 20 mEq labels denote the amount of potassium within the tablet. (Russo, Tr. 3415).

33. There are at least 23 potassium supplements on the market. (Russo, Tr. 3414; SPX 2209-31; CX 17).

34. Reports from the IMS database reflect that the potassium chloride supplement category includes a number of products, including K-Dur 10 and 20, Micro K, Micro K 10, Slow K, K-Tab, Klor Con 8, Klor Con 10, Klor Con M10, Klor Con M20, as well as other general tablet/capsules and generic forms of potassium chloride. (USX 1010; Bresnahan, Tr. 889-90).

35. Managed health care offers many choices of oral potassium chloride supplements. There were at least 24 different combinations of brand and generic potassium chloride products listed on the 2001 United Healthcare Preferred Drug List. (Goldberg, Tr. 154; USX 277).

36. As of 2001, there were numerous branded and generic potassium chloride products on Merck-Medco's formulary. (Teagarden, Tr. 207, 216-17; CX 56; CX 57). A formulary is a list of drugs that the physicians keep on hand to determine what products and what portion of the cost the managed care organization will reimburse to the patient. Dritsas, Tr. 4648.

37. Medco, a pharmacy benefit manager and Merck-Medco's predecessor, regards 10 mEq and 20 mEq potassium chloride products to be "competing." (Teagarden, Tr. 226; USX 131 at Merck-Medco 000206).

2. Potassium chloride products are therapeutically equivalent

38. The demand for a potassium supplement "begins when a patient goes in to a physician and they're treated for

hypokalemia, so the doctor would write a prescription for KCl." (Dritsas, Tr. 4644; Bresnahan, Tr. 696).

39. If a physician prescribes a specific amount of potassium, any potassium chloride product would be effective. (Freese, Tr. 4951-52). A prescription for 20 mEq of potassium could be satisfied with a potassium chloride powder, effervescent, or liquid. (Freese, Tr. 4953-54; USX 410 at 190301). Because potassium products are all therapeutically interchangeable, a pharmacist could dispense 20 mEq of potassium chloride in whatever product form is appropriate for the patient. (Freese, Tr. 4956).

40. At maintenance, a physician will typically prescribe approximately 40 mEqs of potassium per day. (Russo, Tr. 3423). If a doctor writes a prescription for K-Dur 20, a patient will take two tablets (one tablet two times a day, with meals). (Russo, Tr. 3423-24). If a patient's prescription is written for a 10 mEq product, the patient will have to take four 10 mEq tablets, likely two in the morning and two in the evening. (Russo, Tr. 3424).

41. Just because a potassium chloride product is not AB-rated to K-Dur 20 does not mean that it is not therapeutically interchangeable for K-Dur 20. (Dritsas, Tr. 4689-90; CX 740).

42. The FDA's designation of a generic pharmaceutical as "AB-rated," rated or bioequivalent, to a pioneer drug does not necessarily define the product market for antitrust purposes. (Addanki, Tr. 5684). Professor Bresnahan incorrectly defined the relevant market as consisting of 20 mEq tablets and capsules; and a 20 mEq tablet is not bioequivalent to a 20 mEq capsule. (Addanki, Tr. 5684; Bresnahan, Tr. 675; CX 1586). An AB-rated generic is substitutable for the branded product, but that does not mean that the AB-rated generic is the only potential substitute for the branded product. (Addanki, Tr. 5684).

43. K-Dur 20's 20 mEq dosage does not give it a therapeutic advantage over other potassium chloride products. (Russo, Tr. 3421).

44. K-Dur 20 is therapeutically interchangeable with two Klor Con 10s. (Dritsas, Tr. 4655-56). There is no category of patients who can only take K-Dur 20 and not two Klor Con 10s. (Dritsas, Tr. 4661).

45. Two 10 mEq tablets would effectively release in a patient's stomach at approximately the same rate as one 20 mEq tablet. (Goldberg, Tr. 174-75). If a pharmacist were to give a patient two Klor Con 10 tablets, rather than a K-Dur 20, the patient would simply take the two Klor Con tablets at the time that he was supposed to take the one K-Dur 20 tablet. (Dritsas, Tr. 4660-61).

46. Upsher-Smith's 1996 marketing plan for its Klor-Con potassium products shows that the various release mechanisms for different potassium chloride products all delivered potassium, and therefore were therapeutically equivalent and comparable. (Dritsas, Tr. 4693-94; USX 1549; USL 13859).

47. Dr. Addanki looked at whether there were side effect differences between different potassium chloride products that affected their substitutability for each other. (Addanki, Tr. 5693). The primary side effect associated with potassium chloride products is the possibility of gastrointestinal (GI) irritation. (Addanki, Tr. 5693-95). Gastrointestinal irritation is not a substantial problem, however, as its incidence is low for all oral potassium chloride supplements. (Addanki, Tr. 6163). K-Dur 20 does not eliminate this potential GI side effect. (Addanki, Tr. 5693-95). Thus, potential side effect issues do not affect the substitutability of other potassium chloride products for K-Dur 20. (Addanki, Tr. 5695).

48. Although Schering's marketing strategy for its K-Dur 20 product was to emphasize that it could increase patient compliance, there is no significant difference in patient

compliance between K-Dur 20 and Klor Con 10. (Dritsas, Tr. 4662).

3. Customers viewed K-Dur 20 and other potassium chloride products as interchangeable

49. According to Complaint Counsel's witnesses, oral potassium chloride products are therapeutically equivalent.

50. Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. Goldberg, Tr. 126-27. Goldberg testified that most, if not all, potassium chloride products are therapeutically equivalent. Goldberg, Tr. 144 (discussing USX 277, United HealthCare's Preferred Drug List). Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. Goldberg, Tr. 144.

51. Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM") testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. Teagarden, Tr. 234 (discussing USX 125); Tr. 240 (discussing USX 127). He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medco did not even list K-Dur 20 as a prescription drug on its formulary. Teagarden Tr. 239-44. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmaceutical companies. USX 127 at 176; USX 128 at 186.

52. Merck-Medco has consistently regarded potassium chloride products with different delivery systems as clinically equivalent and therefore interchangeable. (Teagarden, Tr. 249-50; (USX 123; USX 124; USX 125).

53. Merck-Medco equates microencapsulated tablets and capsules with wax matrix potassium chloride products. (Teagarden, Tr. 232, 247-48, 250; USX 123-25). Merck-

Medco views branded and generic liquids, sustained release tablets and capsules, effervescent tablets, and powder potassium chloride supplements as alternative products substitutable for one another. (Teagarden, Tr. 233-34, 237-38, 240, 243, 255-56; USX 125; USX 127; USX 128; USX 126; USX 690). In addition, 8 mEq and 10 mEq products consistently are listed as substitutable alternatives on Merck-Medco's formularies. (Teagarden, Tr. 234, 240, 243-44, 256; USX 125; USX 127; USX 128; USX 690).

54. All the potassium chloride products on Merck-Medco's 2001 formulary are listed in the same therapeutical class. (Teagarden, Tr. 223-24; USX 131).

55. All the oral potassium chloride products on United Healthcare's Preferred Drug List are therapeutically equivalent. (Goldberg, Tr. 144-45).

56. Decision-makers at HMOs do not place a premium on K-Dur's delivery system or dosage form. (CX 13 at SP 003045; Addanki, Tr. 5691).

57. Physicians viewed K-Dur 20 as a product for which there were numerous other alternatives. (Dritsas, Tr. 4834). In 1995, 71 percent of the prescriptions for potassium chloride supplementation were being written for products other than K-Dur 20. (Addanki, Tr. 6174; CX 13). As of August 1997, 6 out of 10 potassium chloride prescriptions were for something other than K-Dur 20. (Bresnahan, Tr. 1279).

58. A company could compete with K-Dur 20 simply by convincing a physician to change his prescribing habits. (Dritsas, Tr. 4690).

59. There was significant substitution back and forth between Klor Con 10 and K-Dur 20. (Dritsas, Tr. 4752; Addanki, Tr. 5702). Pharmacists were substituting two Klor Con 10s for one K-Dur 20. (Dritsas, Tr. 4834).

4. Schering viewed K-Dur 20 as competing in the same market as other potassium chloride products

60. Schering measures the sales performance of K-Dur 20 against the entire potassium chloride supplement market, including other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. (Russo, Tr. 3420; CX 18 at 23 000041; CX 17 at 003951, 003954; CX 20 at 00434). Schering's marketing plans indicate that there are over 20 different potassium chloride supplements, all competing in the same market. (Russo Tr. 3414-15; SPX 2209-2231; CX 17). Professor Bresnahan relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. (Bresnahan, Tr. 816). Bresnahan did not consider key portions of Schering's documents that show Schering considered K-Dur to be a part of a larger potassium chloride market. (Bresnahan 709-13, 721, 814-17, 824-25).

61. A 1996 Schering marketing backgrounder states that "K-Dur competes in a crowded $264 million potassium market which continues to grow ...." (Russo, Tr. 3412; CX 17, CX 746; Bresnahan, Tr. 720-21).

62. Schering's 1997 K-Dur Marketing Plan lists competing potassium chloride tablets and capsules. (SPX 977 at SP003849).

63. Schering perceived that K-Dur's major competitors were Klor Con and generic potassium chloride. (CX 20; Bresnahan, Tr. 827). A number of Schering documents characterize generic 10 mEq forms of potassium chloride as Schering's "major competitors." (Bresnahan, Tr. 1170).

5. Upsher-Smith viewed its potassium chloride products as competing in the same market as the other potassium chloride products

64. Upsher-Smith believed it was competing against everyone selling potassium chloride, including K-Tab, Micro-K, Ethex, K-Dur, and Slow K. (Addanki, Tr. 5711; SPX 1050). Upsher-Smith focused on the entire potassium chloride market and did not differentiate between dosage strengths. (Dritsas, Tr. 4692).

65. Upsher-Smith's documents indicate that it was looking at the entire potassium chloride market in positioning its Klor Con 10 potassium chloride product. (Dritsas, Tr. 4692; Addanki, Tr. 5711).

66. In its 1996 market share projections, Upsher-Smith assumed that the potassium market, which included K-Dur 10, K-Dur 20 and all other potassium products, was a $218 million market. (Dritsas, Tr. 4700; USX 1549 at USL 13858).

67. A 1996 marketing plan for Klor Con tablets indicates that the major competitors to Klor Con 8 and 10 were K-Tab, Micro-K 10, Ethex and K-Dur 20. (Dritsas, Tr. 4691-92, 4696; USX 1549 at USL 13858).

68. An Upsher-Smith training manual, dated June 3, 1997, listed a variety of 10 mEq products competing in the potassium market, including Klor Con 10, K-Tab 10, Klotrix 10, Kaon-Cl, Apothecon's product Micro-K 10, ESI, Medeva, Ethex, K-Dur 10, K-Dur 20 and K-Plus 10. (Dritsas, Tr. 4738-39; USX 630 at USL 15331). The manual listed a number of 8 mEq potassium products in the market, including Klor Con 8, Slow K, Copley 8, Warner Chilcott 8, Kaon-Cl 8, Abbott 8, Micro-K 8, and K-Plus 8. (Dritsas, Tr. 4739; USX 630 at USL 15332). Potassium powders in the market were Klor Con 20, Klor Con 25, K-Lor powder, Kay Ciel powder and Klor-vess powder 20. (Dritsas, Tr. 4739; USX 630 at USL 15333). K-Lor powder is marketed by Abbott Laboratories, a major, multi-billion dollar

pharmaceutical company. (Dritsas, Tr. 4739-40). Finally, at least two effervescent tablet products were in the potassium market, Klor Con/EF and K-Lyte. (Dritsas, Tr. 4740; USX 630 at USL 15333).

69. Upsher-Smith's marketing documents reflect the fact that K-Dur 20 "competes directly against the 8 and 10 mEq strengths" of Upsher-Smith's Klor Con. (Bresnahan, Tr. 845; Dritsas, Tr. 4689, 4696; CX 740).

6. The substantial substitutability among potassium chloride products was reflected in actual competition between them

(a) Upsher-Smith directly targeted K-Dur 20 by emphasizing the substitutability of Upsher-Smith's Klor Con 10 mEq product

70. Upsher-Smith built demand for its Klor Con potassium chloride products based on therapeutic substitution. (Dritsas, Tr. 4653).

71. In order to compete against Schering's K-Dur 20, Upsher-Smith's sales representatives informed physicians and managed care organizations that they could more cheaply substitute two Klor Con 10 tablets for one K-Dur 20 tablet. (Dritsas, Tr. 4622-23).

72. In August 1999, Upsher-Smith employed a tactic to encourage high prescribers of K-Dur 20 to prescribe two 10 mEq tablets instead of one K-Dur 20. (Dritsas, Tr. 4765-66; USX 484 at USL 03330).

73. K-Dur 20 tablets are scored, making them easier to break in half. (Freese, Tr. 4955). Because many patients had to break the large K-Dur 20 tablet in half to swallow it anyway, patients could save money by taking two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4622-23). Upsher-Smith's Klor Con 10 wax matrix tablet was about the same size as half a K-

Dur 20 tablet. (Dritsas, Tr. 4624; Freese, Tr. 4955). Klor Con 10 was easier to swallow, though, because a halved K-Dur 20 tablet was bulky with rough edges. (Dritsas, Tr. 4624). Klor Con 10 was round and aqueous coated, a good alternative for patients complaining about swallowing a big tablet. (Dritsas, Tr. 4624).

74. Upsher-Smith implemented therapeutic switch incentive programs through its telephone sales force by targeting high volume K-Dur pharmacies, through visits to the headquarters of chains, wholesalers and managed care organizations, and by targeting long term care and select chains. (Dritsas, Tr. 4754-56; USX 1551 at USL 13795). Upsher-Smith also sent direct mail to high K-Dur prescribers about the cost savings of using two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4756-58; USX 1551 at USL 13795).

75. Direct mailings emphasized the quality of Klor Con and the 56 percent savings. (Dritsas, Tr. 4766; USX 484 at USL 03328). These mailings continued through November 1999. (Dritsas, Tr. 4766-67; USX 484 at USL 03331).

(b) Schering competed against other potassium chloride products

76. During the 1996 -1997 period, Klor Con 10 sales increased 33 percent, moving from 12 percent of total prescriptions to 16 percent. (Bresnahan, Tr. 831). Generic potassium chloride sales increased during the same period, moving from 29 percent to 30 percent of total prescriptions by 1997. (Bresnahan, Tr. 832).

77. This growth was coming at K-Dur 20's expense. (CX 746 at SP 23 00039; Bresnahan, Tr. 743-45, 477; CX 18; SPX 901). Generic competition was growing at K-Dur 20's expense, in part because of the generics' price advantage, in part because of efforts to substitute two 10 mEq tablets for one K-Dur 20, and also because of managed care's role in requiring the use of

generics. (Addanki, Tr. 5708, 5732-33; SPX 993 at SP 290039; CX 20 at SP 004040).

78. Schering expected that losses to 10 mEq generics would worsen over time. "As physicians change their prescribing habits and as the senior population moves into the managed care setting, the branded portion of the market will decrease and the potential for K-Dur volume growth will be limited." (CX 13 at SP 003046). Documents from the March 1995 time frame reflect concerns that staff HMO "decision makers do not place a premium on K-Dur's unique delivery system and dosage form." (CX 13 at SP 003047; Bresnahan, Tr. 717).

79. In 1995, Schering developed a marketing strategy to address competition from generic 10 mEq products. (CX 13 at SP 003046; Bresnahan, Tr. 715-16). Schering sought to develop brand awareness of, and brand allegiance to, the K-Dur brand to prevent an anticipated loss of market share to generic competition. (Bresnahan, Tr. 714-715; CX 13 at SP 003044-48).

80. As of July 1996, Schering was aggressively marketing K-Dur to gain sales from generic potassium chloride products. (CX 718 at SP 23 00039; Bresnahan, Tr. 742). Schering began a targeted mail series to promote K-Dur 20 in an effort to "blunt the continued growth of generic potassium usage." (CX 718 at SP 23 00054); Bresnahan, Tr. 758; CX 18 at SP 23 00039). Schering ran a significant number of promotional programs over a ten-year period that heavily promoted and marketed both its K-Dur products. (Russo, Tr. 3418-19).

7. Brown Shoe factors not addressed in the preceding sections

a. No industry or public recognition of distinct markets

81. Complaint Counsel's expert, Dr. Bresnahan, admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product that has unique features. (Bresnahan, Tr. 711-12; 1271-72).

82. No studies exist comparing patient compliance for K-Dur 20 and the Klor Con 8 mEq and 10 mEq wax matrix products. (Dritsas, Tr. 4662; Kerr, Tr. 6907- 08).

83. IMS, the authoritative industry data source, lists a number of products and manufacturers under its single potassium supplement category numbered 60110. (Dritsas, Tr. 4709-12; 4800-01; USX 619 at 14884-996; USX 822 at 1-12). Schering's K-Dur 20 product is included in the IMS listing with all of the other potassium products. (Dritsas, Tr. 4709; USX 822 at 1). Professor Bresnahan concedes that "all economic researchers ... working in this industry use" IMS data. (Bresnahan, Tr. 471). In fact, Bresnahan himself relied on IMS data for the graph in CX 1596. (Bresnahan, Tr. 735).

b. No peculiar characteristics and uses

84. There are no peculiar characteristics or uses for K-Dur 20. (F. 38-59).

c. No unique production facilities

85. The K-Dur 10 and K-Dur 20 mEq products are produced in the same Schering facility. (Bresnahan, Tr. 1272).

86. Upsher-Smith purchases from Reheis, the same company that supplies the active ingredient for both the wax

matrix Klor Con 8 and 10 and sustained release Klor Con M10 and M20. (CX 263 at 170356.).

d. No distinct customers

87. There is no distinctive class of customers based on "demographics or other classification criteria" that prefer K-Dur 20. (Bresnahan, Tr. 707). K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-Lyte, Klotrix, Apothecon KCL and Ethex potassium chloride products are all prescribed for the same purpose of treating potassium deficiency. (Bresnahan, Tr. 1271; Dritsas, Tr. 4662).

88. There is no special group of patients that can only take K-Dur 20 and can not take other potassium products such as Klor Con. (Dritsas, Tr. 4661).

e. No distinct prices

89. In 1997, K-Dur had the same relative price as other potassium chloride supplements. (Teagarden, Tr. 224, 215, 218). During this time period, branded potassium products had "comparable" prices to K-Dur 20. (Bresnahan, Tr. 730). K-Dur and other potassium chloride supplements have "approximately the same" price. (Russo, Tr. 3426).

90. Dr. Bresnahan presented no statistical pricing study (Bresnahan, Tr. 1274), and did not even have pricing data for K-Dur 20, K-Dur 10, Klor Con 10 or for any other competitors (Bresnahan, Tr. 834-35. 867). During 1997, some potassium chloride products were more expensive than K-Dur 20. (Addanki, Tr. 5741-42; SPX 2069 at 1).

91. Dr. Bresnahan conceded that a pricing difference alone does not suffice to prove a separate product market. (Bresnahan, Tr. 1002). Prices of products that compete in a relevant market need not be close to one another because

competition can occur in other dimensions. (Addanki, Tr. 6198).

92. Professor Bresnahan did not conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. (Bresnahan, Tr. 689-90, 810).

93. Professor Bresnahan did not study the price trend of K-Dur 20 since September 1, 2001, when new entry occurred in the market. (Bresnahan, Tr. 1003).

94. Upsher-Smith launched Klor Con M10 on September 1, 2001. (Dritsas, Tr. 4827).

95. Upsher-Smith launched Klor Con M10 aggressively against K-Dur 10 simultaneously with the launch of Klor Con M20 against K-Dur 20. (Troup, Tr. 5486-88).

96. Just prior to the launch of Klor Con M10, K-Dur 10 sales began to fall dramatically beginning in the summer of 2001 and continuing through November 2001. (Dritsas, Tr. 4827; USX 1557). K-Dur 20 sales followed the same trend in the summer of 2001 and continued though November 2001. (Dritsas, Tr. 4823; USX 1586).

97. Upsher-Smith launched Klor Con M10 in the midst of K-Dur supply problems that began earlier in the summer of 2001, just prior to the launch of Klor Con M10. (Troup, Tr. 5488-89). Due to the lack of availability of K-Dur, Upsher's potassium chloride sales were already on the rise, when Klor Con M10 and M20 were launched into the market. (Troup, Tr. 5488-89).

98. Upon its entry into the market with Klor Con M10. Upsher-Smith had a significant sales increase in its potassium chloride products. (Troup, Tr. 5489-90). Upsher-Smith had record sales of wax-matrix potassium chloride products in the year 2001 as well. (Troup, Tr. 5490).

99. While Upsher-Smith enjoyed strong sales for its Klor Con M10 product, this was due partially to the supply shortages Schering faced for both K-Dur 20 and K-Dur 10, due to FDA

compliance issues that arose during the summer of 2001. (Dritsas, Tr. 4682, 4825).

100. Upon the launch of Klor Con M10 as a generic substitute to K-Dur 10, mandated state substitution for low cost generic alternatives took effect in several states. (Dritsas, Tr. 4824-25). These laws frequently block the prescribed branded product from being dispensed when a generic alternative is available, and thus prevent competition from the branded product completely. (Addanki, Tr. 5748-49; Dritsas, Tr. 4824-25). Similarly, in the K-Dur 20 market, state substitution laws that mandated substitution by a generic alternative negatively affected Schering's sales. (Dritsas, Tr. 4682, 4825).

101. K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. (CX 62 at SP 089326-27). K-Dur 10 sales performed just as Schering's K-Dur 20 performed. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. (CX 62-65).

102. Professor Bresnahan incorrectly asserts that K-Dur 20 is a monopoly (Bresnahan, Tr. 8147), but he concedes that K-Dur 10 was not a monopoly. (Bresnahan, Tr. 8146-47; Addanki, Tr. 5740).

103. While K-Dur 10 was not a monopoly product, K-Dur 10 sales fell just as dramatically as K-Dur 20, when Klor Con M10 became available on September 1, 2001. (Addanki, Tr. 5739-40; Dritsas, Tr. 4823-28; USX 1586; USX 1557).

f. Price sensitivity

104. Price is a major competitive factor in the potassium supplement market. (Dritsas, Tr. 4715-16; USX 626 at 15228).

105. Generic potassium products competed vigorously on price with branded potassium products, taking away sales and market share. (Dritsas, Tr. 4715-18, 4724-25, 4752-53, 4770-

72; USX 626 at 15228; USX 1551 at 13791; USX 425 at 1002952).

106. K-Dur 20 lost some market share to other potassium chloride products. (CX 18 at 23 00045, CX 20 at 004040; Dritsas, Tr. 4717-18, 4752-53). K-Dur 20 also took market share and sales from other potassium products. (Dritsas, Tr. 4719- 20, 4724-25, 4742, 4752, 4841; CX 19 at 15228).

107. Generic manufacturers, such as Apothecon, increased their sales of potassium supplements with lower prices, suggesting price sensitivity and an ability to gain share at the expense of other products in the market with lower prices. (Dritsas, Tr. 4763-64, 4770-72, 4909-10; Addanki, Tr. 6176-79; CX 50 at 13474; USX 380 at 142328; USX 425 at 1002952.).

108. Upsher-Smith's Dolan wrote that a firm may have a gain in sales after cutting prices. Slow-K, for example, showed a unit increase of 41% from 1994 to 1995 while their dollar share continued to decline. (Addanki, Tr. 6181).

(i). Schering K-Dur prices were sensitive to other potassium supplement prices

109. According to Schering, the pricing of K-Dur 20 was depressed due to generic potassium competition. (Russo, Tr. 3416).

110. The 30% price difference between K-Dur 20 and the unbranded generic potassium products caused the sales of the generic products to rise, as noted in the 1998 K-DUR Marketing Plan. (CX 20 at 4040).

111. Schering's price for K-Dur 20 was not the highest for potassium chloride supplements during this time other products were both lower and higher than K-Dur 20 for a 20 mEq dose. (Addanki, Tr. 5741; SPX 2069). IMS data shows that in 1997, K-Tab 10 was the highest priced potassium chloride product. (Addanki, Tr. 5742; SPX 2069). Between 1996 and 2000, K-Dur 20 was never the highest priced potassium chloride

supplement. (Addanki, Tr. 5743; SPX 2068). Schering's K-Dur 20 competed on price with other potassium chloride products by using discounts and rebate programs. (Addanki, Tr. 6172-73).

112. Professor Bresnahan testified that he did not compare Schering's prices against other potassium products' pricing in forming his opinion as to the relevant market in this litigation. (Bresnahan, Tr. 725, 867).

113. Professor Bresnahan also did not measure the cross-elasticity of demand between competing potassium products in conducting his analysis of the potassium market and K-Dur 20. (Bresnahan, Tr. 810).

(ii.)Schering paid large rebates

114. The annual rebates Schering-Plough paid to its customers for K-Dur for 1995 were $21.005 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K-Dur for 1996 were $28.659 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K Dur for 1997 were $17.593 million. The annual rebates Schering-Plough paid to its customers for K-Dur for 1998 were $34.565 million. (CX 695 at SP 020699). The annual rebates Schering-Plough paid to its customers for K-Dur for 1999 were $37.602 million. (CX 695 at SP 020700-701). The annual rebates Schering-Plough paid to its customers for K-Dur for 2000 were $35.214 million. (CX 695 at SP 020701). These rebates were "significant" and were "more than 10 percent of the gross sales of K-Dur" in 2000. (Addanki, Tr. 6173-74). In the first six calendar months of 2001, Schering-Plough paid its K-Dur customers $23.530 million in rebates for K-Dur. (CX 695 at SP 020702).

115. From October 1, 1997 to June 30, 2001, Schering-Plough paid its K-Dur customers a total of $136.566 million in

rebates related to its K-Dur product. (CX 695 at SP 020698-0702).

116. The rebates that Schering-Plough paid its K Dur customers after the June 1997 Agreement with Upsher-Smith demonstrate that Schering-Plough "[was] competing on price through rebates" (Addanki, Tr. 6173). The tens of millions of dollars paid to K-Dur customers in rebates is inconsistent with the theory that Schering-Plough was a monopolist in the sale of its potassium products during this time period. (Addanki, Tr. 6173).

117. Professor Bresnahan did not study Schering's rebates at all in connection with his work in this case. (Bresnahan, Tr. 702). Nor did Professor Bresnahan study Upsher-Smith's rebate programs. (Bresnahan, Tr. 702). Further, Professor Bresnahan did not compare the two firms' relative level of rebate spending on potassium chloride (Bresnahan, Tr. 702).

g. No specialized vendors for various potassium products

118. No specialized vendors serve only K-Dur 20 – both Klor Con and K-Dur 20 are dispensed by pharmacies in response to prescriptions written by doctors. (Bresnahan, Tr. 695-96). Both drugs are prescription medications for potassium. (Bresnahan, Tr. 696-97). Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. (Bresnahan, Tr. 696). Demand for both products begins when a patient presents himself to a doctor. (Bresnahan, Tr. 696). Prescriptions are dispensed for both products at pharmacies. (Bresnahan, Tr. 697-99).

E. The '743 Patent and Schering's K-Dur Products

119. Potassium chloride supplements are prescription drugs used to treat potassium deficiency (known as "hypokalemia"), a condition that often arises among individuals who take

diuretic medications used to treat high blood pressure or congestive heart disease. (Goldberg, Tr. 125-26; CX 3 at FTC 190286-89; CX 19 at USL 15229). Potassium deficiency can cause muscle weakness and life-threatening cardiac conditions. (CX 3 at FTC 190286-88; CX 26 at USL 07336; Goldberg, Tr. 125-26; Schering's Answer at ¶ 22; Banker, Tr. 2950).

120. Potassium chloride, the active ingredient in potassium chloride supplements, including K-Dur 20, is not patented. (Schering Answer at ¶ 33; Banker, Tr. 3251).

121. Patent number 4,863,743 ('743 patent) claims a "pharmaceutical dosage unit in tablet form for oral administration of potassium chloride" containing potassium chloride crystals coated with a material comprising ethylcellulose, having a viscosity greater than 40 cp, and hydroxypropoylcellulose or polyethylene glycol. (CX 12 at FTC 0021322). The novel feature claimed in the '743 patent is the particular coating applied to the potassium chloride crystals. The active ingredient, potassium chloride, was a known compound. The coating allows for sustained-release delivery of the potassium chloride. (CX 12 at FTC 0021319-20). Thus, the '743 patent relates primarily to the sustained-release formulation and does not cover the active ingredient itself. (Banker, Tr. 2947; Horvitz, Tr. 3625-27).

122. Key Pharmaceuticals, a division of Schering, owns the '743 patent. The '743 patent, issued on September 5, 1989, covers K-Dur 20 (as well as K-Dur 10, a 10 mEq version of the product) and expires on September 5, 2006. (Schering Answer at ¶ 34; CX 12 at FTC 0021318).

123. K-Dur 20 is a controlled release, microencapsulated, potassium chloride product developed by Key Pharmaceuticals in the 1980s and approved by the FDA in 1986. (Kerr, Tr. 7561). The "20" in K-Dur 20 refers to 20 mEq (millicquivalent), the amount of potassium contained in the 20 mEq dosage form. (Bresnahan, Tr. 489).

124. Complaint Counsel's expert witnesses did not reach an opinion as to whether the '743 patent is invalid or infringed by Upsher-Smith's or AHP's products. (Bresnahan, Tr. 670; Bazerman, Tr. 8568; Hoffman, Tr. 2351).

F. Upsher-Smith's Potassium Products and Patent Litigation

1. Upsher-Smith's ANDA and the initiation of patent litigation

125. On August 8, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor-Con M in two dosage forms, 10 mEq and 20 mEq, as bioequivalent versions of Schering's K-Dur products. (USX 695). Upsher-Smith subsequently amended its ANDA submission to remove the 10 mEq dosage form from consideration, due to the FDA's initial rejection of a biowaiver for the 10 mEq dosage form. (CX 255). The FDA determined that no ANDA filer was eligible to have exclusivity for any 10 mEq dosage form of any generic version of K-Dur. (USX 345).

126. At the time of its ANDA submission, Upsher-Smith was not aware that it was the first ANDA filing referencing K-Dur 20. (Troup, Tr. 5491; Dritsas, Tr. 4666). After amending its ANDA to remove the 10 mEq dosage form, Upsher-Smith submitted a Paragraph IV Certification. (CX 224). On November 3, 1995, Upsher-Smith notified Schering of its ANDA filing and Paragraph IV Certification with respect to the 20 mEq dosage form. (CX 224; Troup, Tr. 5404).

127. On December 15, 1995, pursuant to the time period set forth in the Hatch-Waxman Act, Schering sued Upsher-Smith for patent infringement in the U.S. District Court for the District of New Jersey, alleging that Upsher-Smith's Klor Con M infringed Schering's '743 patent. (USX 677; Kralovec, Tr.

5032; Troup, Tr. 5404). Trial of the patent case was scheduled to begin on June 18 or 19, 1997. (Hoffman, Tr. 3549).

128. No testimony or evidence was offered to show that Schering's filing of the patent litigation against Upsher-Smith was not initiated for the legitimate purpose of defending its patent.

2. Settlement discussions between Schering and Upsher-Smith

129. In the patent litigation, Schering alleged that Upsher-Smith's Klor Con M20 product infringed the '743 patent because [redacted] [redacted] [redacted] (Banker, Tr. 5254-55; SPX 2258; SPX 2259). Schering also asserted that [redacted] [redacted] [redacted] [(Banker, Tr. 5257-59:16; SPX 2258; SPX 2260).

130. In its answer to Schering's complaint, dated January 29, 1996, Upsher-Smith denied that its product infringed "any claim of the '743 patent," and asserted, as affirmative defenses, that the claims of the '743 patent were invalid and that the '743 patent was unenforceable. (CX 226 at SP 08 00039-41). Upsher-Smith also filed a counterclaim for declaratory judgment that its product did not infringe the '743 patent and that the ' 743 patent was invalid and unenforceable. Upsher-Smith asserted that Schering brought its case with the intention of "trying to delay Upsher-Smith's FDA approval and thereby put off for as long as possible the time when it must face competition from Upsher-Smith's product." (CX 226 at SP 08 00041-42).

131. The patent infringement litigation between Upsher-Smith and Schering was vigorously contested from the outset. (Cannella, Tr. 3815; Kralovec, Tr. 5033; Troup, Tr. 5405-06). As the patent litigation continued through the spring of 1997, Mr. Ian Troup, Upsher-Smith's President and Chief Operating Officer, became increasingly concerned about the toll it was

taking on Upsher-Smith. (Troup, Tr. 5405-06). The litigation was taking longer than Upsher-Smith had anticipated and was particularly rancorous. (Troup, Tr. 5405-07).

132. In April or May 1997, Troup first approached Schering about a possible settlement of the litigation. (Troup, Tr. 5397, 5408-09). The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation. (F. 129-62).

133. The initial settlement meeting look place between Mr. Martin Driscoll, Vice President of Sales and Marketing for Key, and Troup at Schering's office in Kenilworth, NJ on May 21, 1997. (Troup, Tr. 5409). Troup stated that he wanted to obtain through settlement the earliest possible date to launch Klor Con M20 without incurring the damages that could arise from patent infringement. (Troup, Tr. 5411-12). Troup suggested to Driscoll that they settle the litigation by setting a date certain for Upsher-Smith to enter the market with its Klor Con M products sometime before September 2006, the expiration date of Schering's K-Dur patent. (Troup, Tr. 5410-11).

134. At this settlement meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher-Smith's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. (Troup, Tr. 5412). Troup stated that Upsher-Smith wanted to be on the market at an earlier date and that it would have problems with money and cash flow if its entry was delayed until 2005. (Troup, Tr. 5413).

135. The parties met again at Upsher-Smith's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Mr. Driscoll and Mr. Raman Kapur, President of Schering's Warrick subsidiary, attended these meetings on behalf of Schering. Mr. Troup and consultant Andrew Hirschberg attended on behalf of Upsher-Smith. (Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions Nos. 7-

9, 11-12; Upsher-Smith Second Admissions Nos. 9-10, 13-14, 22). At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher-Smith's products. (Troup, Tr. 5420).

136. During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. (CX 1511 at 18-19 (Kapur Dep.)). Troup stressed Upsher-Smith's need to replace its lost revenue from not having a generic K-Dur 20 product on the market. (Hoffman, Tr. 3568; CX 1511 at 18-19 (Kapur Dep.)).

137. During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher-Smith's entry into the K-Dur 20 market. (CX 1511 at 22-23 (Kapur Dep)). The parties decided to approach settlement by splitting the remaining life on Schering's K-Dur patent. (Troup, Tr. 5424-26). Mr. Troup preferred an earlier date. (CX 1511 at 23-24 (Kapur Dep.)). Mr. Driscoll told Upsher-Smith that the earliest date he could offer for Upsher-Smith's entry was September 2001. (CX 1511 at 23 (Kapur Dep.)). Schering never suggested that it would consider an entry date earlier than September 1, 2001. (Troup, Tr. 5500).

138. At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture for Upsher-Smith research and development. (CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34). They also discussed the possibility that Schering might license one or more Upsher-Smith products, including cholestyramine, pentoxifylline and Upsher-Smith's sustained release niacin product, Niacor-SR. (CX 1511 at 14, CX 1495 at 62 (Kapur Dep.); SPX 1242 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34). Upsher-Smith described the expected clinical benefits of Niacor-SR, and Schering was aware of the market opportunity for Niacor-SR because it had been involved in

evaluating the market for other, nearly identical projects. (CX 1495 at 70-71; SPX 1265 at 73 (Driscoll Dep.)). Troup was willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, as Upsher-Smith had no presence in Europe or elsewhere internationally. (Troup, Tr. 5432).

139. Prior to the parties' next face-to-face negotiation session, Mr. John Hoffman, Schering's General Counsel, spoke to, Mr. Nick Cannella, Upsher-Smith's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. (Cannella, Tr. 3824-25). Hoffman told Cannella that Schering viewed the upcoming meeting as an opportunity to discuss potential business opportunities between Schering and Upsher-Smith, not as an occasion to debate the merits of the underlying patent case. (Cannella, Tr. 3826; Hoffman, Tr. 3541). Hoffman stated that Schering "was not going to be paying Upsher-Smith to stay off the market." (Hoffman, Tr. 3541).

140. Prior to the parties' next face-to-face negotiation session, Troup and Hirschberg discussed what Upsher-Smith should ask for in exchange for a license to Niacor-SR. (Troup, Tr. 5448). Hirschberg recommended that Mr. Troup ask for $100 million for a Niacor-SR license. (Troup, Tr. 5448).

141. Upsher-Smith representatives, Troup, Cannella and Hirschberg, and Schering representatives, Hoffman, Kapur, and Jeffrey Wasserstein, Vice President of Business Development, met in Kenilworth, N.J. on June 12, 1997. (Troup, Tr. 5436-38; Hoffman, Tr. 3539, 3541-42). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher-Smith's generic version of K-Dur. (Troup, Tr. 5439). Mr. Troup stated at the June 12 meeting that Upsher-Smith still had "cash needs" because all of the company's cash was tied up in two products in development, Upsher-Smith's generic version of K-Dur and its sustained release niacin product, Niacor-SR. (Hoffman, Tr. 3543).

142. Hoffman stated to Troup that the September 1, 2001 entry had already been negotiated, and that Schering wanted to discuss licensing opportunities. (CX 1509 at 49 (Hoffman Dep.); Troup, Tr. 5439-40). Mr. Hoffman told Mr. Troup that Schering would be "willing to do arm's length business deals that stand on their own two feet, and that's what we're here to discuss." (Hoffman, Tr. 3544).

143. Before the June 12, 1997 meeting Upsher-Smith required Schering to sign a confidentiality agreement regarding Upsher-Smith Niacor-SR product information. (CX 1041). Troup brought to the meeting a confidential printed presentation about Upsher-Smith's Niacor-SR product. (Troup, Tr. 5436-37; CX 1041). This presentation was similar to the presentations Upsher-Smith provided to Searle and the European companies interested in licensing Niacor-SR. (USX 538; CX 1023). Troup also provided Schering with two draft protocols for conducting post-market studies for Niacor-SR. (CX 714; CX 1043).

144. Troup confirmed that Upsher-Smith's offer of a Niacor-SR license extended only to non-NAFTA territories. (Hoffman, Tr. 3545; Troup, Tr. 5440-41). Schering was disappointed that Upsher-Smith would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. (Troup, Tr. 5443-44). Kapur also expressed his continued interest in Upsher-Smith's cholestyramine and pentoxifyilline products. (Hoffman, Tr. 3545).

145. The parties discussed the market potential for Niacor-SR. (Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868). Upsher-Smith told Schering that late-stage clinical work on Niacor-SR was finished and that Schering would be able to get on the European market with Niacor-SR soon. (Troup, Tr. 5441-43). Schering and Upsher-Smith discussed niacin combination therapy, the advantages of Niacor-SR versus

immediate release niacin, the flushing side effects and Niacor-SR's effects on Lp(a). (Troup, Tr. 5583-87). Troup referred to Kos Pharmaceutical's niaspan product, and Kos's market capitalization, to show that Upsher-Smith's Niacor-SR niacin product had tremendous potential. (Troup, Tr. 5583-87; Cannella, Tr. 3829-30).

146. The June 12, 1997 meeting included a preliminary discussion concerning the price of the Niacor-SR product. Troup asked for $70-80 million in his first offer to Schering. (Troup, Tr. 5449; Hoffman, Tr. 3545; SPX 1242 at 44-45 (Kapur Dep.); Cannella, Tr. 3830). Schering told Upsher-Smith it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher-Smith about its interest in pursuing a deal for Niacor-SR. (Hoffman, Tr. 3545-46; Cannella, Tr. 3832). The parties also discussed the potential licensing of other Upsher-Smith products, including Prevalite and Pentoxifylline. (Troup, Tr. 5445-46; Hoffman, Tr. 3544-45).

147. Shortly before or after the June 12, 1997 meeting with Upsher-Smith in Kenilworth, Kapur and Driscoll briefed Mr. Raul Cesan, Schering's president of pharmaceuticals worldwide, on the Upsher-Smith negotiations. (CX 1510 at 66-67; SPX 1242 at 29-30 (Kapur Dep.)). Driscoll and Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher-Smith, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. (SPX 1242 at 30 (Kapur Dep.)). Cesan asked Kapur to contact Mr. Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. (SPX 1242 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.)).

148. Following Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin

product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth $60 million to Schering. (Lauda, Tr. 4342-43). Kapur did not tell Lauda that this licensing opportunity was connected to patent litigation. (Lauda, Tr. 4344).

149. Lauda asked Mr. Jim Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform an assessment of Upsher-Smith's Niacor-SR product. (Lauda, Tr. 4344). Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert may have had. (Lauda, Tr. 4404). Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware that the Niacor opportunity had any connection to a patent suit. (Audibert, Tr. 4113).

150. Kapur sent Upsher-Smith's Niacor-SR data package to Audibert after receiving it from Troup. (CX 1511 at 40 (Kapur Dep.)). Audibert did not recall Lauda specifying a deadline for his review of Niacor-SR, but he knew from past experiences with similar requests that Lauda usually wanted the assessment to be completed quickly. (Audibert, Tr. 4112-13).

151. Audibert provided a formal written assessment of the commercial value of Niacor-SR, dated June 17, 1997. (SPX 2). Although Audibert did not complete his written assessment until June 17, 1997, Audibert and Lauda discussed Audibert's assessment before Audibert completed it. (Lauda, Tr. 4345; CX 1483 at 30 (Audibert I.H.)). In summary, Audibert concluded that Niacor-SR offers a $100+ million sales opportunity for Schering. (SPX 2, at SP 1600045.) Annual dollar sales projections, in millions, were $45 (1999), $70 (2000), $114 (2001), $126 (2002). (SPX2, at SP 1600046-47). Detailed findings on Audibert's analysis and conclusions are set forth at F. 243-57.

152. The next meeting between Schering and Upsher-Smith took place on June 16, 1997, in Upsher-Smith's office in Plymouth, Minnesota. (Troup, Tr. 5452; Hoffman, Tr. 3550). Kapur, Hoffman, Wasserstein and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher-Smith. (Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834). Discussion at the June 16 meeting focused on the valuation of the package of Upsher-Smith products, including Niacor-SR and pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. (Troup, Tr. 5453). Over the course of the meeting, Upsher-Smith offered to license to Schering for the ex-NAFTA countries its wax matrix 8 and 10 mEq products and Klor Con M20. (Troup, Tr. 5453). Troup still wanted $80 million and talked again about the fact that Kos' market capitalization was $400 million based on the strength of Kos' similar niacin product, for which Kos had projected annual sales of $250 million by the third year. (Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835). Schering made a counter-offer of $60 million, which was accepted by Upsher-Smith. (Cannela, Tr. 3835; Troup, Tr. 5458).

153. The parties discussed, either at the June 16 meeting or shortly thereafter, that the $60 million would be paid in installments. (Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511 at 74-75 (Kapur Dep.)). To bridge the gap between Upsher-Smith's asking price and Schering's counter-offer, the parties negotiated milestone payments for launch of Niacor-SR in nine different countries throughout the world, including $2 million for Japan and $1 million each for eight other countries, totaling $10 million in milestones. (CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59). Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to $50 million and a 15% royalty on annual net sales in excess of $50 million. (Troup, Tr. 5459; CX 347 at SP 12 00195).

3. Final negotiations and the June 17, 1997 Agreement

154. Following the June 16, 1997 meeting, the parties' first efforts to create a written agreement produced competing drafts. (Cannella, Tr. 3842-44). The final details of the agreement, including the amounts of the installment payments that would make up the $60 million in up-front royalties, were worked out in a series of telephone calls between the parties over the next 24 hours. (CX 1511 at 74-76 (Kapur Dep.); Hoffman, Tr. 3548-50; Troup, Tr. 5459-60, 5464; Cannella, Tr. 3843-44).

155. After the conference calls to fine-tune the agreement, the agreement was memorialized in writing in an initial fax copy in the early hours of June 18, 1997. (Troup, Tr. 5464; Hoffman, Tr. 3549-50). The settlement agreement, CX 347, bears the date of June 17, 1997. (CX 347; Hoffman, Tr. 3550). However, it was actually signed at 2:00 or 3:00 a.m. on June 18, 1997. (Hoffman, Tr. 3550; Troup, Tr. 5467). Troup signed a fax copy on June 18 (Troup, Tr. 5467), and a hard copy of the final version on June 19, after returning to the office from a business trip. (Troup, Tr. 5465, 5467-68; CX 348).

156. The critical terms of the June 17, 1997 Agreement (CX 348) are set forth below:

> IX. This Agreement constitutes a binding agreement between the Parties with respect to the subject matter set forth herein, conditioned solely upon the approval of the Board of Directors of Schering-Plough Corporation (the "Board"). This Agreement will be presented to the Board at its regularly scheduled meeting to occur on June 24, 1997.
>
> X. Failure of any party to perform its obligations under the Agreement (except the obligation to make

payments when properly due) shall not subject such party to any liability or place them in breach of any term or condition of the Agreement to the other party if such failure is due to any cause beyond the reasonable control of such non-performing party ("force majeure"), unless conclusive evidence to the contrary is provided. Causes of non-performance constituting force majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule material, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right ....

¶ 3 Upsher-Smith agrees that it will not market in the United States its KLOR CON M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001. Effective as of September 2001, Upsher-Smith shall have a non-royalty bearing non-exclusive license under the '743 patent to make, have made, import, export, use, offer for sale and sell its, KLOR CON M 20 and KLOR CON M 10 potassium chloride tablets in the United States ....

¶ 4 Each of Upsher-Smith and Schering shall stipulate to the dismissal without prejudice of the action known as Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., U.S.D.C., D.N.J. (Civil Action No. 956281 (WHW)).

Paragraphs 7, 8, 9, and 10 grant Schering or its designated affiliates, the "SP Licensee," exclusive licenses for NIACOR-SR, KLOR CON 8, KLOR CON 10, KLOR CON M20, PREVALITE, and Pentoxifylline. For each of the drugs except PREVALITE, the territories of the exclusive licenses are all countries other than Canada, the United States, and Mexico. For PREVALITE, the territories are all countries other than Canada and Mexico (and in different packaging in the U.S.)

¶ 11 In consideration for the licenses, rights and obligations described in paragraphs 1 though 10 above, the SP Licensee shall make the following payments to Upsher-Smith:

(i) An up-front royalty payment of twenty-eight million dollars ($28,000,000) within forty-eight (48) hours of the date on which the Agreement is approved by the Schering-Plough Corporation's Board of Directors (the "Approval Date").

(ii) An up-front royalty payment of twenty million dollars ($20,000,000) on the first anniversary of the Approval Date.

(iii) An up-front royalty payment of twelve million dollars ($12,000,000) on the second anniversary of the Approval Date.

(iv) Milestone payments due within ten (10) days of the first commercial sale of NIACOR-SR by the SP Licensee or

its sublicensee in each of the following countries ....

¶ 12 In the event that any court or governmental authority or agency rules that the licenses granted to the SP Licensee are void or invalid, then all such rights which are ruled to be invalid shall terminate and Upsher-Smith shall have the right, at its sole discretion, to purchase back, for nominal consideration, all such terminated rights. Any of Schering's payment obligations under the Detailed Agreement relating to such invalidated rights which have not become due and payable prior to the date of such ruling shall thereupon terminate.

157. The June 17, 1997 agreement achieved two purposes: (1) a settlement agreement of the patent infringement litigation whereby Schering agreed to grant Upsher-Smith a royalty-free license to enter the market with Klor Con M20 and Klor Con M10 on September 1, 2001 (five years before the expiration of Schering's patent on its K-Dur products) (Troup, Tr. 5461-63; Hoffman, Tr. 3548; CX 348); and (2) a license agreement for six separate products, and a related supply agreement for each of the six licensed products. (Troup, Tr. 5509, 5461-63; CX 348).

158. Paragraph 3 states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup, Tr. 5469-70). Schering

wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement. (Troup, Tr. 5470). No other restrictions on any of Upsher-Smith's other products were intended by the settlement agreement. (Troup, Tr. 5470; Cannella, Tr. 3849-50).

159. The license from Schering to Upsher-Smith for the '743 patent covers the marketing and sale of both Klor Con M20 and Klor Con M10 in the United States, even though Klor Con M10 was not a subject of the patent infringement lawsuit or a part of Upsher-Smith's ANDA filing. (Troup, Tr. 5470-72; Kerr, Tr. 6253-54; CX 348).

160. Paragraph 11 of the settlement agreement discusses royalty payments, which refers to the licenses for the six products: Niacor-SR, cholestyramine, Pentoxifylline, and the three potassium products. (Troup, Tr. 5473-74, 5631- 33).

161. Paragraph 11 contains a reference that payment was in consideration of licenses, rights, and obligations described in paragraphs 1-10 of the entire agreement. (Troup, Tr. 5473-74; CX 348). The term "SP Licensee," by whom consideration was paid, only appears in Paragraphs 7 through 10 of the settlement agreement dealing with licenses, and not in Paragraphs 1 through 6, which involve only the settlement of the patent infringement litigation. (Troup, Tr. 5472-73, 5631-33).

162. No fact witness testified that the payments provided for in the June 17, 1997 agreement were not for Niacor-SR and the other products Schering licensed from Upsher-Smith.

4. Schering's Board of Directors approves the June 17, 1997 Agreement

163. The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. (Cannella, Tr. 3855-56; CX 347 at SP 12 00190). The presentation to Schering's Board sought authorization to enter into the license

agreement with Upsher-Smith. (CX 338). It states that, during the course of Schering's discussions with Upsher-Smith, Upsher-Smith "indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty four months to make up for the income that they had projected to earn from sales of Klor-Con had they been successful in their suit." (CX 338 at SP 12 00270). The Board was informed that Schering had made it clear to Upsher-Smith that any such deal would have "to stand on its own merit, independent of the settlement." (CX 338 at SP 12 00268). One Schering Board member testified that "it was made very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement." (SPX 1225 at 30 (Becherer Dep.)). Another Board member explained that "the licensing agreement that was being proposed would have to stand on its own merits," so that it "would be an agreement that would make sense in and of itself independent of anything else." (CX 1526 at 24-25 (Russo Dep.)).

164. The Board presentation provided sales projections for Niacor-SR of $100 million plus in annual sales. (CX 338 at SP 12 00268). The presentation showed a net present value of $225-265 million for the Niacor license. (CX 338 at SP 12 00275).

165. The Board presentation provided sales forecasts for sales of prevalite, pentoxifylline, and Klor-Con 8, 10 and M 20 "to be $8 million a year in the first full year of launch, growing to $12 million a year in the second full year, and then gradually declining in year four and thereafter. Net margins on the products are expected to be between 35% and 50%." (CX 338 at SP 12 00271).

166. A Board member testified that "[t]he focus of this proposal was a licensing agreement for four products in a space that Schering was interested in for a $60 million investment and a $225 million plus economic value return. So, from the

Board's standpoint, there was nothing about this that would cause any questions." (CX 1526 at 51 (Russo Dep.)). Based on the information presented to them and their understanding that the payments were for the licensed products, the Board approved the license deal. (CX 340 at SP 07 00003).

5. The "any other sustained release microencapsulated potassium chloride tablet" clause was necessary and narrowly constructed to fully settle the litigation

167. Paragraph 3 of the settlement agreement states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added after some discussion between the parties so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup, Tr. 5469-70). Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement. (Troup, Tr. 5470).

168. A narrowly-constructed restriction like the one in the first sentence of paragraph 3 of the agreement is necessary in a patent settlement, as "it's essential to describe what it is that the parties can and can't do." (Kerr, Tr. 6334, 6336, 6338-39). In the pharmaceutical industry, settlement agreements necessitate narrowly-constructed clauses limiting the production of specific compounds, as generics need to be as similar as possible to the branded products and hence defy limitation by general language. (Kerr, Tr. 6338-39).

169. Professor Bresnahan has not identified any other product that was blocked by the language in the June 17, 1997

agreement that allegedly barred Upsher-Smith from marketing "any other sustained release microencapsulated potassium chloride tablet." (Bresnahan, Tr. 984). Nor is Professor Bresnahan aware that either Upsher-Smith or Schering had any product in mind other than the Klor Con M20 product when they drafted their agreement. (Bresnahan, Tr. 984).

170. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were bottlenecked by the limiting clause in paragraph 3. (Dritsas Tr., 4836).

171. Professor Bresnahan conceded that "if the contract were otherwise pro-competitive," it would be reasonable to read the language of the agreement as ruling out a "me-too product that is simply introduced under another name other than Klor Con M20 but is, in fact, Klor Con M20." (Bresnahan, Tr. 985). Such a provision would not be anticompetitive. (Bresnahan, Tr. 987-88, 990-91).

G. Whether the $60 Million Dollars Was a Payment For Fair Value of Niacor-SR

172. Complaint Counsel's expert witness economist, Professor Timothy F. Bresnahan testified that a side deal at fair value did not raise competitive concerns. (Bresnahan, Tr. 932-33.) Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." (Bresnahan, Tr. 964-65. See also Tr. 660-61; 989-90.)

1. The market for cholesterol reducing drugs

173. In the mid-1990s, pharmaceutical companies were interested in the market for reducing cholesterol-reducing

drugs. (Horovitz, Tr. 3623-60). The worldwide market for cholesterol lowering drugs had grown to become the seventh best selling drug class in the world. (SPX 235 at SP 16 00001). In 1997, the global market for cholesterol-reducing drugs was estimated at $6-7 billion. (Kerr, Tr. 6871-72; SPX 225 at 3; Levy, Tr. 1763-64; Kerr, Tr. 6876). Forecasts in 1997 for the cholesterol-reducing drug market indicated that by the year 2000, the world market could total $11 billion. (Kerr, Tr. 6875-76; SPX 225 at 3).

174. Documents available to Schering in June 1997 showed that the market for cholesterol lowering drugs outside the U.S., Canada, and Mexico ("worldwide Ex-NAFTA") was larger than the U.S. market for cholesterol lowering drugs. (SPX 5 at SP 16 00447; CX 1042 at SP 16 00112). Complaint Counsel's pharmaceutical licensing expert, Dr. Nelson Levy estimated that in 1997, U.S. sales represented "roughly" half of worldwide sales of cholesterol lowering drugs. (Levy, Tr. 1914-15).

175. Although relatively inexpensive hyperlipidemic agents, including niacin, had been available for decades, annoying side effects interfered with patient compliance. (SPX 608 at SP 16 00344-345). In the late 1980's, however, the market for cholesterol lowering drugs began to take off with the widespread use of the newly developed and more expensive HMG-CoA reductase inhibitors, known as the statins. (SPX 608 at SP 16 00345). In the mid-1990's, there were five classes of cholesterol lowering drugs, including the statins that dominated the market, the fibrates, the bile acid sequestrants, niacin and probucol. (SPX 235 at SP 16 00001).

176. Niacin, or nicotinic acid, is a B vitamin that was first discovered to have hypolipidemic qualities in 1955. (SPX 608 at SP 16 00390). Niacin decreases LDL (known as "the bad cholesterol"), raises HDL (known as "the good cholesterol"), decreases triglycerides (TGs), and decreases lipoprotenin(a) (Lp(a)). (SPX 608 at SP 16 00390-391; Horovitz, Tr. 3620;

Audibert, Tr. 4099). Niacin has a unique profile in that it is the only drug shown to alter each of these lipids in the desired direction, and is one of the most effective compounds in increasing HDL. (Halvorsen, Tr. 3903; Horovitz, Tr. 3620; Levy, Tr. 1761; CX 1042 at SP 16 00072). Niacin's effectiveness in reducing total cholesterol, LDL cholesterol and triglycerides, as well as raising HDL cholesterol, has been demonstrated in numerous independent studies over the past 30 years. (USX 21 at 0077; USX 308 at 110462-64).

177. Niacin is also one of the only compounds known to decrease Lp(a). (SPX 608 at SP 16 00390-391; Halvorsen, Tr. 3903; SPX 235 at SP 16 00002). Prior to 1997, several studies had associated Lp(a) with atherosclerosis and CAD, and treatment of Lp(a) was considered by European and U.S. experts to be one of the major unmet needs. (SPX 608 at SP 16 000362; SPX 235 at SP 16 00003; SPX 924 at SP 002780; CX 1042 at SP 16 00068-69).

178. In addition to its known efficacy profile when used as monotherapy, niacin had also been shown prior to 1997 to be an effective agent when used in combination with other cholesterol lowering drugs, such as statins. (SPX 608 at SP 16 00382, 391; Freese, Tr. 4962-64, 4989; SPX 52 at FTC 110463-110464; USX 141 at Moreton 00082; CX 1042 at SP 16 00074). As a result, physicians also prescribe niacin in combination with statins. (Horovitz, Tr. Tr. 3670; Brown, Tr. 3146-47; Freese, Tr. 4989).

179. Despite niacin's known profile as an effective cholesterol reducing agent, the immediate release formulations of the drug were not widely used prior to 1997 due to a side effect known as flushing. (Horovitz, Tr. 3620-21, 3625-26; USX 141 at Moreton 00082; SPX 924 at SP 002781; Audibert, Tr. 4100). Flushing is a result of increased blood flow near the skin, which causes redness, tingling and itching in almost all patients who use niacin. (Horovitz, Tr. 3625-26; Halvorsen, Tr. 3906; Brown, Tr. 3150). Although flushing does not present a

safety risk, it is a nuisance side effect that significantly reduces patient compliance. (Halvorsen, Tr. 3906; Horovitz, Tr. 3620-21, 3625-26; Audibert, Tr. 4105). This flushing side effect prevented widespread use of what was recognized in the pharmaceutical industry as an otherwise effective cholesterol lowering agent. (Horovitz, Tr. 3620-21; Audibert, Tr. 4099-100).

2. Upsher-Smith's Niacor-SR and other products relevant to the settlement agreement

a. Development and testing of Niacor-SR

180. Upsher-Smith began the Niacor-SR (Sustained Release) development program in 1991. (Kralovec, Tr. 5010). Niacor-SR is a sustained-release formulation of niacin, meaning that it releases niacin gradually over a period of time. (Halvorsen, Tr. 3901; Horovitz, Tr. 3624). The purpose of sustained-release niacin is to eliminate flushing. (Halvorsen, Tr, 3905-06).

181. In 1997, both Upsher-Smith and another pharmaceutical company, Kos Pharmaceuticals, were each involved in the advanced stages of development for obtaining FDA approval of their own sustained-release niacin products. (Troup, Tr. 5474-75; USX 21 at 76-77). Upsher-Smith's Niacor-SR product presented an opportunity for Upsher-Smith to expand its sales in an extremely large market of cholesterol-reducing drugs. (Halvorsen, Tr. 3902-03).

182. By spring 1997, Upsher-Smith believed that it had completed all of the clinical development work on Niacor-SR, and was preparing to file its NDA for Niacor-SR. (Troup, Tr. 5474-75). As early as 1995, Upsher-Smith had conducted and completed the patient phase of two Phase III pivotal studies -- the last phase of clinical development for gaining approval of a drug product by the FDA with over 900 patients. (Halvorsen,

Tr. 3907). By July of 1996, the last of 300 patients had completed testing in two additional longer-term Phase III follow-on studies. (Halvorsen, Tr. 3911; CX 1019 at 175679). By June 1997, Upsher-Smith was in the process of developing and performing a short, 17-day, 38-healthy-volunteer pharmacokinetic study on Niacor-SR and was finalizing an individual and integrated study report so that Upsher-Smith could file its NDA. (Halvorsen, Tr. 3907).

183. As part of its Phase III testing for Niacor-SR, Upsher-Smith conducted two pivotal studies, as required by the FDA, the 920115 and 900221 studies. (Halvorsen, Tr. 3907-08). Upsher-Smith also conducted two longer term follow-on studies - the 920944 and 900837 studies. (Halvorsen, Tr. 3907-08). The last patient in the last of the four studies, the 920944 study, completed treatment in July 1996. (Halvorsen, Tr. 3909). The results of the Phase III studies available in June 1997 confirmed the safety and efficacy of Niacor-SR as a cholesterol-reducing drug. (Horovitz, Tr. 3641-42, 3658).

184. In addition to clinical safety and efficacy tests, the FDA requires a pharmacokinctic test ("PK test") for approval of an NDA submission. (Halvorsen, Tr. 3937). This test measures how a drug is absorbed and eliminated in the human body. (Halvorsen, Tr, 3936-37, 3939). The subject is dosed and then serial blood draws or urine samples are taken over time, for example hourly, with the purpose of plotting the concentration of the drug in the plasma or urine over time. (Halvorsen, Tr. 3936-37). In March 1997, the FDA ultimately agreed with Upsher-Smith that a multi-dose PK test was unnecessary for approval of the Niacor-SR NDA, and indicated that Upsher-Smith could seek approval based on a single-dose urine PK test. (Halvorsen, Tr. 3938-41; CX 917 at 107426-27; USX 281).

185. As of June 1997, Niacor-SR was Upsher-Smith's primary research project and was a highly valued asset. (Troup, Tr. 5474-75). By the second quarter of 1997, Upsher-

Smith had spent $13 million developing Niacor-SR - more than double all of Upsher-Smith's other projects combined. (Halvorsen, Tr. 3902; Dritsas, Tr. 4833).

186. In 1994, Upsher-Smith's market research showed a potential market for Niacor-SR of $100 to $400 million in 2000. (Kralovec, Tr. 5011-12). As of spring 1997, Upsher-Smith believed Niacor-SR had the potential to be a very successful product, with revenues of at least $50 to $100 million, and possibly as much as $250 million. (Freese, Tr. 4978, 4990; Kralovec, Tr. 5011; Dritsas, Tr. 4829, 4831-32).

b. Upsher-Smith's comparison of Niacor-SR to Kos' Niaspan and cross-license agreement with Kos

187. In the mid-1990s, Kos Pharmaceuticals ("Kos") developed Niaspan, a sustained-release niacin product, which released niacin in a controlled dosage form for cholesterol therapy. (Patel, Tr. 7497; Halvorsen, Tr. 3945; Horovitz, Tr. 3640). Based on information available to Upsher-Smith in 1997, Niacor-SR and Niaspan were virtually the same in terms of efficacy and safety. (Halvorsen, Tr. 3947-48, 3960; Troup, Tr. 5524-25; Kerr, Tr. 6292; Horovitz, Tr. 3626, 3660; Lauda, Tr. 4351; Levy, Tr. 1315). During 1996 and 1997, Upsher-Smith's Director of Clinical and Regulatory Affairs, Dr. Mark Halvorsen continually kept track of the information on Niaspan that was publicly available. (Halvorsen, Tr. 3945-47; USX 535).

188. Comparing Kos's statements regarding Niaspan's performance on all of the lipid parameters – Lp(a), LDL, HDL, triglyecrides – and Kos' statements regarding the safety profile of Niaspan to Niacor-SR's clinical and safety results, Dr. Halvorsen was confident in June 1997 that Niaspan and Niacor-SR were virtually identical. (Halvorsen, Tr. 3945-47; USX 535). Upsher-Smith executives believed Kos's Niaspan to be

a direct and major competitor to Niacor-SR. (Kralovec, Tr. 5025; Halvorsen, Tr. 3946-47; Kerr, Tr. 6297).

189. By February 7, 1997, Kos and Upsher-Smith had negotiated and agreed on a cross-license under which [redacted][redacted][redacted](Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9). [redacted] (Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9).

190. This agreement did not affect Upsher-Smith's ability to license its Niacor-SR product for sales outside of the United States. (Kralovec, Tr. 5027- 28; Troup, Tr. 5479-80). In fact, the agreement explicitly allowed Upsher-Smith to license its extra-U.S. rights under the patent to third parties. (Troup, Tr. 5655-56; Kerr, Tr. 6462; CX 568 at 145288).

191. The financial market expected Kos' Niaspan product to be very successful. (Kerr, Tr. 6292-93; USX 1606). On April 21, 1997, investment firm Dillon Reed forecast that Niaspan sales would reach $250 million by 2001 -- roughly the same amount that Upsher-Smith had estimated for its sales of Niacor-SR. (Kralovec, Tr. 5025-26; USX 535 at USL 11515; SPX 225 at 2). In May 1997, analysts at Dillon Reed estimated product revenues for Niaspan of $17.3 million for 1998, growing to $242.8 million in 2001. (Kerr, Tr. 6827-28; 6832-33; USX 239). Other investment reports at that time forecast Niaspan sales of $20 million in 1997, growing to $250 million in 2000. (Kerr, Tr. 6876-77; SPX 225).

192. The investment community's valuation of Kos Pharmaceuticals in the first half of 1997 bolstered Upsher-Smith's expectations for Niacor-SR. (Kralovec, Tr. 5025-26; Troup, Tr. 5441-43; USX 535).

c. Upsher-Smith's efforts to license Niacor-SR

193. In order to reach the maximum level of sales for Niacor-SR, Upsher-Smith believed that it would have to spend

$15 20 million to develop an effective sales force. (Kralovec, Tr. 5012-13).

194. Upsher-Smith saw great potential for Niacor-SR outside the U.S. market, but lacked a sales or marketing representative outside of North America. (USX 154-55; Freese, Tr. 4978; Kralovec, Tr. 5016; Troup, Tr. 5476; Halvorsen, Tr. 3970-71). By mid-1996, Upsher-Smith began actively looking for a Niacor-SR licensing partner for the European market. (Kralovec, Tr. 5028-29; Troup, Tr. 5476; Halvorsen, Tr. 3965). Upsher-Smith planned to market Niacor-SR in North America on its own and so did not discuss U.S. licensing of Niacor-SR with potential licensees. (Freese, Tr. 4977-78; Kralovec, Tr. 5016; Troup, Tr. 5431- 33, 5440-41).

195. By the end of May 1997, Upsher-Smith's efforts to find a European partner for Niacor-SR had progressed to the point where Upsher-Smith representatives were holding face-to-face meetings with potential licensees to discuss licensing opportunities. (Freese, Tr. 4976-77; Halvorsen, Tr. 3965; Troup, Tr. 5475-76; Kralovec, Tr. 5020-21; USX 596-98; CX 880). These Upsher-Smith representatives reported to senior management that they were enthusiastic about finding a licensing partner. (Kralovec, Tr. 5020-21).

196. In the first week of June 1997, Upsher-Smith executives were in Europe meeting with four potential licensing partners for Niacor-SR: Servier, Pierre Fabre, Esteve, and Lacer. (Halvorsen, Tr. 3871, 3967, 4026; Kralovec, Tr. 5028-29; Troup, Tr. 5476; Horovitz 3767; USX 596-98; CX 880). Upsher-Smith executives believed that potential European licensing partners were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. (Kralovec, Tr. 5017-18; 5020-21). As of June 1997, none of the four potential licensing partners for Niacor-SR had turned down Niacor-SR. (USX 596; USX 1523 at 58-59 (O'Neill Dep.); Kerr. Tr. 6321, 6818, 6815-16).

d. Other Upsher-Smith products relevant to the June 17, 1997 Agreement

197. In 1997, in addition to its niacin and potassium supplement families of products, Upsher-Smith had several other drugs on the market, or near market stage, including Pentoxifylline, Prevalite and Pacerone. (Dritsas, Tr. 4618-19, 4832-33; Troup, Tr. 5420-21, 5445). Although Upsher-Smith had plans for marketing these products in the United States, it lacked the presence and resources to market the drugs outside of North America. (Dritsas, Tr. 4636, 4833; Troup, Tr. 5431-32).

198. Prevalite, a bile acid sequestrant called cholestyramine, was another cholesterol fighting drug sold by Upsher-Smith. (Dritsas, Tr. 4618-19). Prevalite was a branded generic similar to Bristol-Myers Squibb's branded product Questran/Questran Light. (Dritsas, Tr. 4813-18; USX 591; USX 660). In 1996, Upsher-Smith had sales for Prevalite of $7 million, with 1997 projected sales at $8.8 million. (Dritsas, Tr. 4804-05, 4812-13; USX 591; USX 440; USX 627 at 15277).

199. Pentoxil, Upsher-Smith's trade name for Pentoxifylline, was another generic drug that was under development at Upsher-Smith in 1997. (Halvorsen, Tr. 3981). Pentoxifylline is used to treat peripheral intermittent claudication. Pentoxifylline allows red blood cells to be more flexible so that they may pass into blood vessels that have decreased in size and deliver oxygen. (Halvorsen, Tr. 3981). By June of 1997, Upsher-Smith had completed and submitted to the FDA all the clinical studies required for approval of its ANDA for Pentoxifylline as a generic form of the Trental brand of Pentoxifylline. (Halvorsen, Tr. 3981082). In 1997 alone, Trental sales were $153 million (Rosenthal, Tr. 1740). Trental's Pentoxifylline patent was set to expire in July 1997, and in June 1997, Upsher-Smith expected to be among the first generics approved to enter the market after the expiration of the

patent. (Halvorsen, Tr. 3983). At that time, Upsher-Smith's internal market projections estimated that Upsher-Smith's Pentoxifylline would realize $4.4 million sales in 1998. (USX 668 at 20666).

200. Pacerone, Upsher-Smith's trade name for an amiodarone product, was under development at Upsher-Smith in 1997. Pacerone is used to treat ventricular tachycardia, or rhythm management for the heart. (Dritsas, Tr. 4637-38, 4833). In June of 1997, Upsher-Smith believed that Pacerone was an important product and estimated first year sales of Pacerone would be $10 million. (Troup, Tr. 5446).

3. Schering's interest in and valuation of Niacor-SR

a. Schering's interest in Kos' sustained release niacin product, Niaspan

i. Schering's negotiations with Kos

201. Kos filed an NDA for Niaspan with the FDA in May 1996. (SPX 18). Schering was interested in Niaspan in early 1997. Schering believed that a sustained release niacin product that solved flushing caused by immediate release niacins and did not elevate liver enzymes to the degree that some over-the-counter sustained release niacins had done could be commercially successful. (CX 1494 at 85; CX 1495 at 73 (Driscoll Dep.); SPX 1265 at 73 (Driscoll Dep.); Audibert, Tr. 4116-17).

202. Schering was interested in Niaspan not only as a late stage product that could generate revenues in the near term, but also because it presented an opportunity for Schering to enter the cholesterol lowering market in advance of its launch of ezetimibe, a drug that Schering was developing for the cholesterol market. (Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771).

203. In 1997, Mr. Raymond Russo was Key's marketing director for cardiovascular products in the United States. (Audibert, Tr. 4110; Russo, Tr. 3433-34). Russo participated in the negotiations with Kos regarding its Niaspan product. (Russo, Tr. 3449). James Audibert was Ray Russo's counterpart responsible for territories outside the United States and was for a time involved in the negotiations with Kos regarding Niaspan. (SPX 1224 at 77 (Audibert Dep.); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439).

204. By the time of Schering's discussions with Kos, the FDA had completed its medical review of Niaspan, and was discussing labeling with Kos. (Russo, Tr. 3445; CX 543; Audibert, 4102, 4105). The fact that the medical review had been completed meant that the FDA had judged the product to be safe and efficacious, and that it was just a matter of finalizing the actual labeling on the product before approval by the FDA. (Audibert, Tr. 4105-06).

205. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. (Russo, Tr. 3449). Under a co-promotion arrangement, the parties would split efforts in the field force and divide the cost of the marketing. (Russo, Tr. 3449). A co-promotion arrangement differs from a license, in which the company licensing the product would retain all control and all sales proceeds after royalties are paid. (Russo, Tr. 3449- 50). Also, in a license arrangement, the licensee alone would be responsible for all the expenditures, investment and strategic direction associated with the product. (Russo, Tr. 3449).

206. Martin Driscoll, Schering's Vice President of Sales and Marketing for Schering's Key division, thought Kos' product labeling looked interesting. (CX 1495 at 96 (Driscoll Dep.); Driscoll, Tr. 1420, 2702). Schering asked Kos for more information, including Niaspan's clinical results supporting the

labeling. (CX 1495 at 96 (Driscoll Dep.)). Kos was not forthcoming with additional information. (CX 1495 at 97-98 (Driscoll Dep.); SPX 1265 at 97-99 (Driscoll Dep)).

207. Kos wanted to maintain control over Niaspan's marketing and strategic positioning, while its partner gave Niaspan primary promotional positioning. (SPX 18). Kos wanted to have Niaspan promoted by Schering's sales representatives in the "primary position," meaning that it would be the first product a sales representative would discuss in a doctor's office. (Audibert, Tr. 4106). Schering explained that it could not guarantee that Niaspan would always be in the primary position because Schering had its own products, such as Claritin, that would be detailed first during particular seasons. (Audibert, Tr. 4107). Kos also wanted guarantees with respect to the level of call activity, asking for specific numbers of specific types of calls through the launch period. (Russo, Tr. 3451). Schering did not feel that it could accommodate the level of call activity that Kos wanted. (Russo, Tr. 3451). Schering would be more comfortable with secondary detailing. (Patel, Tr. 7555). Kos wanted "absolute maximum commitment from Schering in the form of first line details." (Patel, Tr. 7555). And, Kos also was demanding strategic control over the marketing and promotion of Niaspan. (Driscoll, Tr. 1423; Patel, Tr. 7557). Schering and Kos also discussed the issue of who would "book" sales. (Patel, Tr. 7556). Booking sales refers to which company records the sales that have been made. (Patel, Tr. 7556). Kos wanted to record, or "book," Niaspan's sales to show significant sales as a company. (Patel, Tr. 7556).

208. Audibert viewed Kos' demands as "unrealistic in terms of what their expectations were from us" regarding co-promotion activity. (Audibert, Tr. 2448). Audibert viewed Kos' demands for support from Schering's sales force as irrational, and very difficult for Schering to agree to. (Audibert, Tr. 4106).

ii. Schering's evaluation, market research, and forecasts for Niaspan

209. On February 11, 1997, the information about Niaspan that Schering had been able to obtain from Kos was sent to Schering's cardiovascular licensing group, which includes Audibert. (Audibert, Tr. 4102; SPX 924). Audibert was asked to evaluate a Niaspan co-promotion deal, in which Schering would be promoting the product along with Kos, from the perspective of Global Marketing. (Audibert, Tr. 4100-01).

210. In his discussions with Kos and evaluation of Kos' materials, Audibert learned that it was possible to develop a sustained-release niacin product that was both safe and effective. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2452-53; SPX 18; SPX 21). For Audibert, Niaspan proved that the concept of a sustained release niacin that reduced flushing and solved liver toxicity issues could work. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2454, Tr. 4115-16). Kos told Schering that Niaspan had a very low incidence of elevated liver enzymes. (Audibert, Tr. 4105). Kos referenced a study by Dr. McKinney using a particular sustained release niacin on the market at that time. (SPX 18; Audibert, Tr. 4104).

211. Schering performed market research in the United States to determine doctors' interest in sustained release niacin. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). The market research included telephone interviews with ten prominent lipidologists who had attended Schering's recent meetings in New York concerning ezetimibe, another drug of Schering. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). Schering found that doctors would welcome a sustained release niacin product that reduced flushing and avoided liver toxicity issues, but would want more evidence that the product met those needs. (Russo, Tr. 3532; CX 576).

212. Schering was hopeful that Niaspan's delivery system would overcome the experts' reservations regarding sustained

release niacin and flushing, liver toxicity and diminished efficacy. (Russo, Tr. 3503, 3509). Accordingly, Schering wanted to see the rest of the NDA filing for Niaspan for additional data that would support Kos' representations. (Russo, Tr. 3511). Schering also wanted to see the final labeling submitted to the FDA for Niaspan because Schering believed that if it showed no contraindications and a better side effect profile than other niacin products, Niaspan would be a very good product for Schering. (Russo, Tr. 3511-12).

213. Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. (Russo, Tr. 3455). Part of that process involved an assessment of the product's value to Schering and the preparation of sales forecasts. (Russo, Tr. 3455). Russo forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461 63, 3472); CX 550 at SP 002743; CX 551, at SP 002731). Under this scenario, Russo projected that Schering could achieve $134 million in sales in 2002, rising thereafter to $193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iii. Schering's offer to Kos for Niaspan

214. On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. (Russo, Tr. 3463-64; CX 554; SPX 619). Schering is the only company that gave Kos a written proposal before Niaspan was launched. (Patel, Tr. 7543).

215. [redacted] [redacted] (Russo, Tr. 3589; CX 554). [redacted] [redacted] [redacted] (Russo, Tr. 3590; CX 554; Patel, Tr. 7666). [redacted] [redacted] [redacted] (Russo, Tr. 3590). [redacted] (Russo, Tr. 3589, 3590; CX 554; Patel, Tr. 7665; SPX 6190). [redacted redacted] (Russo, Tr. 3589-90; CX 554). [redacted] (Russo, Tr. 3589,

3590; CX 554; Patel, Tr. 7665; SPX 619). [redacted redacted redacted] (Russo, Tr. 3589; CX 554; Patel, Tr. 7665; SPX 619). [redacted redacted redacted redacted] Patel, Tr. 7666).

216. Schering's proposal did not contain up-front payments to Kos or equity investments. (Patel, Tr. 7605; CX 554).

217. On May 21, 1997, one week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. (SPX 230; SPX 35; Patel, Tr. 7667). Kos did not react favorably to Schering's proposal. (Russo, Tr. 3465). Mr. Dan Bell, Chief Operating Officer of Kos, told Schering that its offer was practically "insulting," and that he was "offended" by it. (SPX 230; [Patel, Tr. 7669].

218. [redacted] (Patel, Tr. 7571/. [redacted redacted] (Patel, Tr. 7531- 32, 7608; CX 556; CX 769). [redacted redacted] (Russo, Tr. 3465-66). [redacted redacted] (Russo, Tr. 3465). [redacted redacted] (Russo, Tr. 3450). [redacted redacted] (Bell, Tr. 7567; Patel, Tr. 7608-09; CX556). [redacted redacted redacted] (Patel, Tr. 7567, 7607-08; CX 556)).

219. After receiving Kos' reaction to Schering's first proposal, Schering did not submit another proposal to Kos. (Russo, Tr. 3466, 3488; CX 558). Schering felt that Kos would be a difficult partner to deal with. (Audibert, Tr. 2450).

iv. Kos' discussions with other potential partners and subsequent sales of Niaspan

220. Kos' Niaspan entered the market in August 1997. (7 Tr. 1404 (Driscoll I.H.)). At the time of Niaspan's launch, Kos was still looking for a co-promotion partner for Niaspan in the U.S. (Patel, Tr. 7577).

221. In the fall of 1997, Kos had conversations with Searle Pharmaceuticals. (Patel, Tr. 7576; Egan, Tr. 7895-96; 7898).

In early November, Searle met with Kos and the parties discussed Kos' demands for a U.S. co-promotion agreement. (CX 524). Kos demanded from Searle a large number of details for Niaspan. (Egan, Tr. 7986-88). Searle found Kos' demands unreasonable. (Egan, Tr. 7982). Kos wanted an up-front payment from Searle in the $10-20 million range. (Egan, Tr. 7982). Kos also wanted a "ridiculous" and unreasonable percentage of the profits from any co-promote arrangement. (Egan, Tr. 7984-85). Searle declined the Kos opportunity. (Egan, Tr. 7980).

222. During the summer and fall of 1997, Kos was also pursuing discussions with SmithKline Beecham concerning a co-promotion arrangement for Niaspan. In August 1997, Kos discussed with SmithKline the broad terms of a potential co-promotion partnership for Niaspan. (Patel, Tr. 7678; CX 508). As with Schering, Kos stated that it needed guaranteed detailing for Niaspan, that Kos wanted to book sales, and that Kos wanted the opportunity to co-promote a SmithKline product. (Patel, Tr. 7678-79; CX 508). SmithKline and Kos also discussed SmithKline's interest in non-U.S. rights to Niaspan. (CX 508). In November 1997, Kos announced disappointing sales results and its stock price dropped. (Patel, Tr. 7685, Tr. 7688); Levy, Tr. 2076-77). Subsequently, SmithKline and Kos did not to enter into an arrangement regarding Niaspan. (Patel, Tr. 7540).

223. Kos had other discussions with potential partners about a European license for Niaspan after November 1997. (Patel, Tr. 7589). [redacted redacted redacted] (Patel, Tr. 7615, 7587). Kos did not find a European partner for its Niaspan product. (Patel, Tr. 7540).

224. Overall, Kos' Niaspan has had a spotty history in the marketplace. (Kerr, Tr. 6329). Initially, Niaspan did not achieve nearly the expected sales levels predicted and Kos' stock price plummeted. (Kerr, Tr. 6329, 6331; USX 1607).

In 1998, Niaspan sales were poor. Sales for the first 6 months of 1998 totaled $3.8 million and in August 1998, after being in the market one year. Niaspan's share of new prescriptions for the month was only 1.1%. (Audibert, Tr. 4159; SPX 15). Total sales for 1998 were only $15 million. (Driscoll, Tr. 1405). Two years after introduction, in 1999, Niaspan's sales were only $37 million. (Kerr, Tr. 6331; USX 1613).

226. After four years, Niaspan is now moderately successful, with last year's sales equal to about $100 million. (Kerr, Tr. 6331).

b. Schering's Evaluation of Upsher-Smith's sustained release Niacin product, Niacor-SR

227. In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product. (Lauda, Tr. 4342-43). Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide EX-NAFTA"). (Lauda, Tr. 4344).

228. Audibert began his review when he received the data package regarding Niacor-SR on June 12, 1997. (Audibert, Tr. 4113; Lauda, Tr. 4344). The package included results from the two phase III pivotal clinical trials conducted by Upsher-Smith to obtain registration of Niacor-SR, referred to by their protocol numbers 920115 and 900221. (Audibert, Tr. 4113-15, 4171; CX 1042; Halvorsen, Tr. 3907-08). The package also included information regarding two draft protocols for phase III-B studies Upsher-Smith was planning to conduct once the NDA

was filed. (Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025). Phase III-B studies are studies conducted not as part of the initial registration of a product, but to support subsequent labeling revisions. (Audibert, Tr. 4114). One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. (Audibert, Tr. 4115; SPX 71-72).

i. Mr. Audibert's qualifications in June 1997

A. Expertise in Sustained Release Products and Cholesterol Lowering Pharmaceutical products

229. James Audibert, who is currently employed within the Schering Plough Research Institute, was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. (Audibert, Tr. 4085, 4092). Audibert received his Bachelor of Science in Pharmacy from Northeastern University College of Pharmacy in 1974, and received his Master of Science in Pharmacology from Northeastern University College of Pharmacy in 1982. (Audibert, Tr. 4081). From 1976 to 1987, Mr. Audibert worked for two companies, both of which specialized in the use of sustained release technology to transform old compounds into new products. (Audibert, Tr. 4082-84).

230. In mid-1986, Schering acquired Key and, in March 1987, Audibert moved to New Jersey to work for Schering's marketing department. In April 1995, Audibert went to work in Schering's Global Marketing Department. (Audibert, Tr. 4085). In this position, Audibert was in charge of cardiovascular products, including cholesterol lowering products. (Audibert, Tr. 4092-93).

231. Audibert's responsibilities included working on a cholesterol-lowering agent Schering had in development called ezetimibe. (Audibert, Tr. 4093). By early-1997, Mr. Audibert began working with the research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. (Audibert, Tr. 4094). As part of this process, Audibert was also conducting a detailed evaluation of the market for cholesterol lowering drugs. (Audibert, Tr. 4094-95).

232. Audibert's detailed evaluation of the cholesterol lowering market included: (1) a review of secondary information and published literature regarding the market and products within the market; (2) conducting primary market research around the world, including interviewing physicians on what they perceived to be unmet needs and future trends in cholesterol management; (3) convening advisory panels to get input from experts in the cholesterol lowering area; (4) attending major cardiology meetings around the world dealing with current and future trends in cholesterol management, and the development of future cholesterol lowering products; and (5) traveling to subsidiaries around the world to meet with national experts and local opinion leaders in cholesterol management. (Audibert, Tr. 4095-96).

233. As part of this process of evaluating the cholesterol lowering market, Audibert studied the profiles of the products that were already available for the treatment of cholesterol, as well as the anticipated profiles of future products, and evaluated what unmet needs existed within the market. (Audibert, Tr. 4097-98). This included studying the major cholesterol lowering products on the market in 1997, including the statins, the fibrates, the resins, and niacin. (Audibert, Tr. 4098). Audibert also conducted a detailed evaluation of the size of the cholesterol lowering market, which included: (1) examining the current size of the worldwide market by product and geographic territory; (2) predicting the future size of the

cholesterol lowering market through conversations with opinions leaders, examination of cholesterol management treatment guidelines, estimation of the impact of future products on the market, and consideration of analyst reports published by the investment community. (Audibert, Tr. 4096-97).

234. [redacted redacted redacted] [(SPX 625 at SP 002914; SPX25 at SP 002899)]. [redacted] [(SPX625 at SP 002914; SPX 25 at SP 002899)].

235. [redacted redacted redacted] (Audibert, Tr. 4301-02; SPX 221 at SP 002895-2898). [redacted redacted] (Audibert, Tr. 4302-04; SPX 231 at SP 002941-2942). [redacted redacted redacted] (Audibert, Tr. 4303; SPX 231 at SP 002944). [redacted redacted redacted] (Audibert, Tr. 4304; SPX 231 at SP 002944)].

236. [redacted redacted redacted redacted] (Audibert, Tr. 4304).

237. Audibert also learned about niacin through his work on ezetimibe. (Audibert, Tr. 4098-99). Audibert was fully aware of the available scientific knowledge regarding niacin, including: the fact that niacin had been known for many years to have a positive effect on various lipid parameters that are important in cholesterol management, including lowering LDL, raising HDL, lowering triglycerides, and lowering Lp(a); the fact that niacin has been shown to be effective in long term morbidity studies; and the fact that niacin was incorporated into the NCEP treatment guidelines which recommend niacin as one of the agents for use in managing cholesterol. (Audibert, Tr. 4098-99). However, Audibert was also acutely aware of the fact that immediate release forms of niacin were limited by the side effect of flushing, and that sustained release niacin dietary supplements had been associated with substantial elevations in liver enzyme levels. (Audibert, Tr. 4100).

B. Involvement in the evaluation of Kos' Sustained Release Niacin Product in Spring 1997

238. On February 11, 1997, the information about Niaspan that Schering had obtained from Kos was sent to Schering's cardiovascular licensing group. (Audibert, Tr. 4102; SPX 924).

239. On March 13, 1997, Audibert and Russo initiated a conference call with Kos to discuss Niaspan. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). During this conversation, Audibert initiated a discussion of Niaspan's side effect profile, including in particular, the success of its sustained release formulation in: overcoming the flushing side effect of immediate release niacin, without causing the significant elevations in liver enzymes reported with over-the-counter sustained release niacin formulations. (Audibert, Tr. 4103-05; SPX 18 at SP 002776; Russo, Tr. 3443-44).

240. Kos advised Audibert that the rate of discontinuation due to flushing had been reduced to about 5% of patients. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). When Audibert raised the issue of liver enzyme elevations, Kos advised Audibert that, in contrast to the McKinney study in which 50% of patients experienced liver enzyme elevations above five times the upper limit of normal, only about 1% of patients in clinical trials with Niaspan experienced elevations of three times the upper limit of normal. (Audibert, Tr. 4103-05; SPX 18 at SP 002776).

241. Kos advised Audibert that it had filed an application for regulatory approval with the United States FDA, and that the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. (Audibert, Tr. 4105; SPX 18 at SP 002776). Because the FDA does not proceed to a discussion of labeling until it has determined a product is safe and effective, the fact that the FDA had completed its medical review and was discussing labeling for Niaspan indicated to

Audibert that the FDA had concluded that Niaspan's sustained release formulation was indeed safe and effective. (Audibert, Tr. 4101-02, 4105-06).

242. In late-March or early-April 1997, Audibert stopped participating as the international contact in the negotiations with Kos. (Audibert, Tr. 4111- 12). Kos had indicated that it was focused on co-promotion of the product in the United States and that promoting Niaspan outside the United States was not a priority. (Audibert, Tr. 4106). Audibert terminated his involvement, in part, because he believed Kos' demands were "totally irrational" and he felt that it was unlikely that the parties would reach an agreement. (Audibert, Tr. 4111- 12).

ii. Mr. Audibert's evaluation of the Niacor-SR opportunity in June 1997

A. Evaluation of market opportunity and product profile

243. Audibert conducted an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity. (Audibert, Tr. 4112). The 52- page data package provided by Upsher-Smith to Schering contained detailed summaries of the results of Niacor-SR's phase III pivotal trials, including all the information that Audibert required to conduct his evaluation of Niacor-SR's clinical profile. (Audibert, Tr. 4113-14).

244. The clinical data from Upsher-Smith's pivotal trials confirmed to Audibert that Niacor-SR was effective, and that it exceeded the regulatory hurdle of an average 15% reduction in LDL cholesterol. (Audibert, Tr. 4123; CX 1042; CX 1484 at 119-21 (Audibert Dep.)).

245. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR had significantly reduced the incidence of flushing as compared to immediate release

niacin. (Audibert, Tr. 4117-19; CX 1042 at SP 16 00088-00089). As compared to immediate release niacin, Niacor-SR reduced the number of flushing occurrences more than four-fold. (Audibert, Tr. 4118-19; CX 1042 at SP 16 00089; Horovitz, Tr. 3645-46).

246. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR caused a very low incidence of liver enzyme elevations. (Audibert, Tr. 4119-20). Audibert concluded that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that seen with cholesterol lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained release niacin products. (Audibert, Tr. 4104-05, 4121, 4124; Horovitz, Tr. 3650-51). In his written commercial assessment, Audibert reported that the fact that some patients experienced liver enzyme elevations with Niacor-SR was consistent with the known side effect profile of the statins. (SPX 2 at SP 16 00044). Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. (Audibert, Tr. 4121-22; CX 1042 at SP 16 00093; Horovitz, Tr. 3649-50).

247. Based on his evaluation of the results of the pivotal trials, Audibert concluded that Niacor-SR was a safe and effective drug that satisfied the unmet need in the cholesterol lowering market that he identified in June 1997. (11 Tr. 4123-24 (Audibert Dep.)). Audibert had seen Kos' Niaspan as the "proof of concept," and he concluded based on the results of Upsher Smith's clinical trials that Upsher-Smith had also used sustained release technology to develop a safe and effective niacin product. (11 Tr. 2453-54 (Audibert Dep.); [Lauda, Tr. 4512-13).].

B. Mr. Audibert's Commercial Assessment of the Niacor-SR Opportunity

248. Having determined that Niacor-SR's product profile satisfied an unmet need in the marketplace, Audibert constructed a forecast of sales based on that product profile in that market. (Audibert, Tr. 4124). The process for constructing this sales forecast included: (1) an evaluation of the current and future size of the cholesterol lowering market; (2) an evaluation of how Niacor-SR would be positioned within that market; (3) an evaluation of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. (Audibert, Tr. 4124-27).

249. First, Audibert evaluated the current size of the market and made a projection of the future growth of that market for a period of ten years. (Audibert, Tr. 4124-25). Mr. Audibert used IMS data representing the current size of the cholesterol lowering market worldwide, excluding the U.S., Canada and Mexico ("worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. (SPX 5). The IMS data indicated that the size of the cholesterol lowering market in those territories in 1996 was $4 billion. (SPX 5). Mr. Audibert's handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. (SPX 5). Audibert estimated an average annual growth 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. (SPX 2 at SP 16 000046). Second, Audibert evaluated how Niacor-SR would be positioned within the cholesterol lowering market, first, as monotherapy and second, in combination with statins. (Audibert, Tr. 4125-26; [SPX 231 at SP 002944)]. Third, Audibert conducted an evaluation of the price at which Niacor-SR could be marketed. (Audibert, Tr. 4125-27). In making this determination, Audibert knew that Niacor-SR's position against

the statins required that he be realistic in terms of pricing for Niacor-SR. (Audibert, Tr. 4126). As a result, he concluded that Niacor-SR would best be positioned as an inexpensive alternative to the statins and he selected a price of just half of atorvastatin, the generic name for Lipitor. (Audibert, Tr. 4126). Finally, Audibert projected what share of the market Niacor-SR could obtain at that price and positioning. (Audibert, Tr. 4126-27). Audibert concluded that Niacor-SR would compete as a low-priced, moderately effective product for the treatment of high cholesterol. (Audibert, Tr. 4126-27). From his experience in talking with cardiologists and health payers internationally, Audibert had learned that many countries with government funded health systems recognized the need to treat high cholesterol, but simply could not afford to treat significant portions of the population with the expensive statins. (Audibert, Tr. 4126-27).

250. Having identified the opportunity to position Niacor-SR as an inexpensive alternative to statins, Audibert still believed that Niacor-SR would only obtain an initial market share of .75%, rising for just two years to 1.5%, and then decreasing thereafter to a 1% share. (Audibert, Tr. 4127-29; SPX 2 at SP 16 00047).

251. Having estimated the overall size of the market and a market share for this product over a ten year period, Audibert used multiplication to determine projected sales. (Audibert, Tr. 4127). Audibert's formal written assessment for Niacor-SR, dated June 17, 1997, includes tables illustrating Audibert's annual projections of market size and market share, from which he calculated annual dollar sales. (Audibert, Tr. 4127-29); SPX 2 at SP 16 00046-47). The sales projected for each of these years, in millions, were:

Sales ($)	1999	2000	2001	2002	2003
Millions	45	70	114	126	116

	2004	2005	2006	2007	2008
	127	140	125	136	149

(SPX 2 at SP 16 00046-47).

252. On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. (Audibert, Tr. 4138-39; SPX 6). The annual profit and loss calculations were created by deducting from his sales forecasts, an estimated 10% cost of goods, as well as the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at $22.8 million in the third year of sales. (SPX 6). Because Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher-Smith. (Audibert, Tr. 4139).

253. Following his evaluation of the Niacor-SR opportunity, Audibert prepared a written commercial assessment, as well as a written profit and loss projection on the basis of the sales he had projected in his commercial assessment. (SPX 2; SPX 6). Audibert provided a copy of each of these documents to Lauda. (Audibert, Tr. 4138-40; Lauda, Tr. 4345-46).

254. In his assessment, Audibert provided background information regarding the cholesterol lowering market, including the competitor products in that market. (SPX 2 at SP 16 00040-45). Audibert explained the current state of knowledge regarding niacin as an effective cholesterol lowering agent, as well as the difficulties that had hampered prior immediate release niacins (flushing) and sustained release niacins (association with hepatotoxicity). (SPX 2 at SP 16 00040-45). Audibert detailed the current size of the cholesterol lowering market, recent growth experienced in that market, and provided an assessment of why the growth of that market was expected to continue. (SPX 2 at SP 16 00040- 45). Audibert identified his conclusion that a product opportunity existed for Niacor-SR, and on the basis of his conclusions, he provided a

summary of his sales projections for Niacor-SR. (SPX 2 at SP 16 00040-45). Audibert attached to his assessment two tables which contained his detailed financial projections of both the future growth of the cholesterol lowering market and his sales projections for Niacor-SR in that market. (SPX 2 at SP 16 00046-47). Audibert concluded that Niacor-SR offers a $100 million sales opportunity for Schering. (SPX 2, at SP 1600045).

255. Niacor-SR also offered strategic value to Schering in June 1997. Schering was developing ezetemibe for the cholesterol market, the projected launch of which was still several years away. (Audibert, Tr. 4094, 4108-09). Because Schering was planning to launch the largest product in company history in a market in which it had no presence, it was important for Schering to first establish a presence in that market in order to build a knowledgeable sales force capable of maximizing the launch of ezetimibe. (Audibert, Tr. 4108-11; Horovitz, Tr. 3622-23, 3659-66; Lauda, Tr. 4348-49; Russo, Tr. 3437-38).

iii. Audibert's sales projections for Niacor-SR were consistent with projections for Niaspan

256. In March 1997, Kos proceeded with an Initial Public Offering ("IPO") on the basis of projected sales of its primary product, Niaspan. (Patel, Tr. 7544; Egan, Tr. 7982; Kerr, Tr. 6982). Around the time of the IPO in the spring of 1997, several market analysts published projected U.S. sales for Niaspan reaching between $220 million and $250 million in the third year of sales. (Levy, Tr. 2072; SPX 226; Kerr, Tr. 6872-73; USX 535 at USL 11514; [Patel, Tr. 7674-75).]

257. In April 1997, Russo, Schering's senior director of marketing in charge of the negotiations with Kos prepared a range of forecasts of potential U.S. Niaspan sales. Russo

forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731). Under this scenario, Russo projected that Schering could achieve $134 million in sales in 2002, rising thereafter to $193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iv. Schering determined that the value of Niacor-SR to Schering in June 1997 exceeded $60 million

258. Following Audibert's evaluation, Lauda and Audibert met to discuss the written assessment and profit and loss statement, including the projected sales that Schering could expect from Niacor-SR, its projected market share, and assumptions underlying those projections. (Lauda, Tr. 4345-46; SPX 2; SPX 6). Lauda concluded that Schering could promote Niacor-SR and "easily garner" the market share that Audibert projected. (Lauda, Tr. 4347-49).

259. Using the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher-Smith called for under the agreement, Schering performed its standard calculation of the economic value for this transaction which confirmed that Niacor-SR presented an economic value to Schering of between $225 to $265 million, and an internal rate of return of 43%. (SPX 26 at SP 16 00275). None of Complaint Counsel's witnesses challenged the validity of Schering's calculation that Audibert's financial projections for Niacor-SR represented an economic value to Schering of between $225 to $265 million, and a return on its investment of 43%. (SPX 26 at SP 16 00275).

260. Schering's expert on pharmaceuticals. Dr. Zola Horovitz, performed his own "conservative" calculations and

concluded that Schering could have paid as much as $100 million and still obtained a 35% internal rate of return and an economic value of $205 million. (Horovitz, Tr. 3617-18). Upon review of the information he relied upon, Dr. Horovitz testified that, based on Schering's projections at knowledge in June 1997, the deal for Niacor-SR would be a good deal for Schering and would stand on its own two feet. (Horovitz, Tr. 3787).

261. Having concluded that the Niacor-SR opportunity presented a value to Schering in excess of $60 million, Lauda advised Kapur of his conclusion and later provided him a copy of Audibert's written assessment and profit and loss projections. (Lauda, Tr. 4349; SPX 2; SPX 6).

4. Schering's And Upsher-Smith's post-deal conduct

a. Schering's internal preparations and communications with Upsher-Smith regarding availability of Niacor-SR data

262. Shortly after Schering's Board of Directors approved the Niacor-SR license, June 24, 1997, (CX 340), Schering began to get the Niacor-SR project organized. On July 2, 1997, Kapur informed Cesan that global marketing would take responsibility for Niacor SR, while Warrick, Schering's subsidiary, would oversee development of the generic products licensed from Upsher-Smith. (SPX 8). At the same time, Kapur notified Lauda that the Niacor-SR deal had been approved and that global marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. (SPX 7; Lauda, Tr. 4350).

263. Schering also contacted Upsher-Smith regarding Niacor-SR and other matters soon after the Schering Board approved the Upsher-Smith license agreement. (SPX 255; SPX

9). On June 30, 1997, Schering's in-house counsel for licensing, Paul Thompson, sent Upsher-Smith a draft of a more detailed Amendment Agreement that expanded on such issues as the supply and delivery of Niacor-SR and other licensed products. (SPX 255; Kralovee, Tr. 5050-51). On July 16, 1997, Kapur wrote to Troup regarding Schering's intention to schedule a visit to inspect Upsher-Smith's facility that manufactured cholestyramine, one of the generic products Schering had licensed from Upsher-Smith. (SPX 9).

264. Audibert attempted to arrange, through Mark Halvorsen, Upsher-Smith's Director of Clinical and Regulatory Affairs, a visit by someone from Schering's clinical research group to Upsher-Smith in order to review Upsher-Smith's data and discuss regulatory filing strategies. (SPX 241; Audibert, Tr. 4142, 4149- 50). On August 21, 1997, Audibert updated Kapur on the Niacor-SR project, explaining that his efforts to arrange this trip to Upsher-Smith had been unsuccessful because of Upsher-Smith's delays in compiling the relevant clinical data and regulatory documents. (SPX 11; Audibert, Tr. 4154-55).

265. Schering continued to communicate with Upsher-Smith regarding its desire to obtain the Niacor-SR data. (SPX 10; SPX 12). On October 21, 1997, Kapur wrote to Troup, asking whether the Niacor-SR clinical data that Schering had expected by mid-October was available and attempting once again to set up a meeting for Schering to review the information at Upsher-Smith's offices. (SPX 12 at SP 05 00014; Audibert, Tr. 4156). A November 7, 1997 memo from Mr. Kapur to Audibert indicates that Troup had agreed that Upsher-Smith would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) were completed. (SPX 12 at SP 05 00013; Audibert, Tr. 4156).

b. Upsher-Smith's internal development efforts on Niacor-SR and communications with Schering

266. After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher-Smith about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. (Troup, Tr. 5481-83). By the end of June, Upsher-Smith and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher-Smith. (USX 732).

267. As of the summer of 1997, Upsher-Smith was going forward with its NDA and Upsher-Smith's primary activity was to complete the final study reports and the ISS/ISE. (Halvorsen, Tr. 3975). The patient phase of all four clinical studies had concluded well before June 1997 and Upsher-Smith was in the process of compiling the data. (Halvorsen, Tr. 3912).

268. In early June 1997, consistent with the FDA's agreement in March 1997 that Upsher-Smith only needed to conduct a single-dose PK test (Halvorsen, Tr. 3940-41; USX 0281). Upsher-Smith prepared a protocol for such a test and started on it immediately. (Halvorsen, Tr. 3941; SPX 331). To conduct the PK test, Upsher-Smith first had to be sure that it had validated a proper bioanalytical method for measuring the drug passed in urine. (Halvorsen, Tr. 3942-45). Upsher-Smith hired two contract research organizations ("CROs") to work separately in competition to develop a final methods validation. (Halvorsen, Tr. 3942-45; USX 562). Simultaneously, Upsher-Smith had them test the protocol with a pilot study using Slo-Niacin so that Upsher-Smith would have samples to use in developing the method for testing Niacor-SR. (Halvorsen, Tr. 3942-45).

269. Upsher-Smith continued throughout the second-half of 1997 to hold its teleconferences with the CROs regarding the study reports, medical narratives and the accompanying medical narratives. (Halvorsen, Tr. 3975; USX 1146). Between June 20 and December 19, 1997, there were 19 more such conference calls. (USX 1146). As of July 22, 1997, the goal was to file the Niacor-SR NDA before the end of the year. (Halvorsen, Tr. 3985; USX 1188 at 093578).

270. During June and July 1997, Upsher-Smith was working on its Niacor-SR package insert to include with its NDA submission. (Freese, Tr. 4990; USX 308). By July 21, 1997, Upsher-Smith had developed a revised draft of its package insert. (Freese, Tr. 4990; USX 308). Upsher-Smith's draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. (Freese, Tr. 4990; USX 308 at 110477-9).

271. Prior to August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data in the first of several communications between the two representatives. (Halvorsen, Tr. 3976-77; USX 189). During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher-Smith had conducted with Niacor-SR for FDA approval -- the two pivotal studies and the two follow on studies. (Halvorsen, Tr. 3976-77; USX 189). On August 14, 1997, Audibert sent Halvorsen a fax to arrange a meeting at Upsher-Smith for the week of September 15. (USX 189).

272. In August 1997, Upsher-Smith was still planning to file its NDA for approval of Niacor-SR at the end of 1997. (Halvorsen, Tr. 3977-78). By telephone call, Halvorsen informed Audibert that he did not believe that there would be clinical data available until late October, and that what Upsher-Smith would have at that time were the final reports from the individual studies, and not the ISS/ISE. (CX 780 at 00236).

273. On August, 15, 1997, Upsher-Smith mailed copies of the four protocols -- the 115, 221, 837 and 955 clinical studies --to Audibert. (Halvorsen, Tr. 3979; USX 727). Mr. Audibert then forwarded this information to Schering's research institute. (CX 780 at 00236).

274. On October 27, 1997, a Schering licensing attorney faxed to Upsher-Smith's CFO, Mr. Paul Kralovec, a copy of the Amendment Agreement with Schering's proposed revisions. (SPX 217 at 0013). On November 12, 1997, Kapur's secretary, responded to Upsher-Smith's October 31 letter regarding the need for Schering to execute a broader confidentiality agreement covering the licensed products, including Pentoxifylline. (USX 218 at 135402).

c. Kos' stock plunge preceded Upsher-Smith's and Schering's decisions not to pursue Niacor-SR projects

275. In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States, which were considerably below what everyone had expected. (Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480). The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos' stock price, which had peaked around $44 per share, plummeted to $5 per share. (Troup, Tr. 5480).

276. Within a few weeks after Kos released the sales information for Niaspan, Upsher-Smith had pulled back on its ANDA project because in order to successfully go forward with a generic product, the branded product must attain a certain level of sales. (Halvorsen, Tr. 3956, 3964). An NDA was equally unpromising, as Niacor-SR was a very similar product to Niaspan, which failed to achieve a large following. (Halvorsen, Tr. 3964). In December 1997, Upsher-Smith put its Niacor-SR development project "on hold status, pending

evaluation of Kos marketing success." (SPX 302 at USL 16165).

277. Although Upsher-Smith decided not to go forward with its NDA for Niacor-SR in the United States, a December 16, 1997 fax reports that Halvorsen informed the Niacor-SR team that there was a possibility that the project would proceed in Europe through Schering. (USX 1226; Halvorsen, Tr. 3987-88). January 15, 1998 meeting minutes indicate that the Niacor-SR project was on hold with "only minimal activity" to continue in most departments. (CX 962 at USL 13253; Halvorsen, Tr. 4051). Halvorsen testified that Upsher-Smith's clinical department proceeded "full forward" at that point with efforts to complete the study reports. (Halvorsen, Tr. 4051). The January 15, 1998 meeting minutes indicate that this continuing work represented "a significant amount of resource hours" for Upsher-Smith. (CX 962 at USL 13252, USL 13253; Halvorsen, Tr. 4051). Upsher-Smith continued to communicate with its CROs in efforts to compile the integrated summary of safety and the draft clinical tables in January 1998. (Halvorsen, Tr. 3988-89; USX 1235).

278. Niaspan's performance in the marketplace was relevant to the Niacor-SR project because it provided a real world opportunity for Schering to test the market. (Audibert, Tr. 4144). By September 1998, Schering no longer believed that Niacor-SR would do as well as it had originally predicted. (Lauda, Tr. 4433-34; Audibert, Tr. 4143-44).

279. A subsequent discussion between Audibert, Kapur and Troup regarding Niacor-SR is summarized in a September 25, 1998 memo from Audibert to Mr. Lauda. (SPX 15). During this discussion, Troup stated that Upsher-Smith was not going forward with its NDA. (SPX 15; Audibert, Tr. 4159). Audibert's memo indicates that this raised some real issues in his mind about the potential commercial viability of Niacor-SR from his perspective. (SPX 15; Audibert, Tr. 4159). He noted that "in August 1998, after being in the market one year,

Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." (SPX 15). He also stated that Upsher-Smith's decision not to pursue its NDA would result in delay and a greater demand on Schering's resources if it proceeded with its European filings. (SPX 15).

280. On October 6, 1998, Kralovee confirmed in a letter to Kapur that Upsher-Smith had suspended all research on Niacor-SR. (CX 1111; Kralovee, Tr. 5058-59; Lauda, Tr. 4428-29). Upsher-Smith cited the poor performance of Kos' Niaspan as one factor in its decision (Kralovee, Tr. 5061-62), as well as the fact that the FDA had requested that Upsher-Smith conduct an additional PK study, which would have delayed Upsher-Smith's NDA and resulted in the product coming to market two or three years behind the launch of Niaspan. (Lauda, Tr. 4429; CX 1111).

281. Schering abandoned its efforts to bring Niacor-SR to market for several reasons. (Audibert, Tr. 4144; Lauda, Tr. 4352-53). The Kos product continued to do poorly in the marketplace, telling Schering that marketing a sustained release niacin product was going to be more difficult than anticipated.(Audibert, Tr. 4144-45). Niaspan's poor performance in the United States had implications for Niacor-SR sales in Europe. (Audibert, Tr. 4145). The fact that Upsher-Smith had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together its international dossier than had originally been anticipated. (Audibert, Tr. 4145). Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. (Audibert, Tr. 4145). As a result, Schering decided not to pursue Niacor-SR further. (Lauda, Tr. 4407).

d. Upsher-Smith continued clinical work and medical writing wrap up and continued to communicate with Schering in 1998

282. Although Upsher-Smith decided in December 1997 to put on hold its plans to obtain FDA approval for Niacor-SR, this did not affect its clinical work on behalf of Schering. (Halvorsen, Tr. 3989). Upsher-Smith continued in 1998 to finalize the clinical study reports and put them in a usable form for Schering. (Halvorsen, Tr. 3989). During 1998, Upsher-Smith remained in contact with Schering-Plough regarding the licensed products. (USX 665, SPX 251; CX 1088; CX 1111).

283. Throughout the first part of 1998, at Upsher-Smith's instruction, its CRO continued to work on the methods validation for the single-dose PK protocol. (Halvorsen, Tr. 3943-44; SPX 331). The CROs working on the reports and medical writing continued their work through March of 1998, and Upsher-Smith's research and development team continued to have their regular telephone conferences to supervise and assist that work. (Halvorsen, Tr. 3924-25:4; 3944-45; USX 1230). Between January 1, 1998 and May 1998, members of Upsher-Smith's research and development team participated in a dozen such calls. (USX 1230; USX 1232 at 903845; Halvorsen, Tr. 3988-95).

284. In a meeting in March of 1998 in the office of Upsher-Smith's president Mr. Troup, Dr. Halvorsen was informed that Schering was not going to seek European approval. (Halvorsen, Tr. 3924-25).

285. On May 13, 1998, a CRO provided to Upsher-Smith the final draft of the Niacor-SR 92044 follow-on study and the related medical narratives. (USX 1265 at 093775; CX 1019). On November 4, 1998, Upsher-Smith received from a CRO its 508-page report containing the final methods validation for the PK test required by the FDA. (Halvorsen, Tr. 3943-44; SPX 333 at 165879). The total cost to Upsher-Smith of performing

this final methods validation was $400,000. (Halvorsen, Tr. 3944). Upsher-Smith was also spending money on its multiple CROs for their clinical work in completing the final study reports, the ISS and the ISE. (Halvorsen, Tr. 3944-45).

286. All totaled, from 1991 through 1998, Upsher-Smith spent $15-16 million on developing Niacor-SR -- four times as much alone than all other product development projects, and more than 80 percent of Upsher-Smith's total research budget during that period. (Kralovec, Tr. 5010-11; Halvorsen, Tr. 3902, 3995; Troup, Tr. 5475).

287. In September 1998, Upsher-Smith's President and Warrick's President, Mr. Kapur, had a discussion regarding the status of Niacor-SR. (Troup, Tr. 5608; Audibert, Tr. 4158-59; CX 1088 at 006-7). Troup reported that Upsher-Smith was not planning to file its NDA for FDA approval. (CX 1088; CX 1111 at SP 05 006-7; Troup, Tr. 5610). Mr. Troup explained that Upsher-Smith was concerned that Kos's Niaspan product had not been successful, even though Kos had invested considerably more sales and promotion effort in the United States that Upsher-Smith planned. (CX 1088 at SP 05 006-7; Troup, Tr. 5480-81; Audibert, Tr. 4159-60).

288. Based on what he knew at the time, Troup also explained that Niaspan appeared to be marginally better than Niacor-SR. (CX 1111). Upsher-Smith believed that because Niaspan had received the results indications for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. (Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60).

289. As Kapur had requested, on October 6, 1998 Paul Kralovec, Upsher-Smith's Chief Financial Officer, provided Kapur written confirmation of Upsher-Smith's decision to suspend its efforts on Niacor-SR. (CX 1111). In the letter, which was also copied to Troup, Kralovee again confirmed the reasons for Upsher-Smith's decision not to proceed with U.S.

approval. (CX 1111). He again explained that based on Kos's approval, Upsher-Smith would have been two to three years behind the launch of Niaspan. (CX 1111).

5. Complaint Counsel has not demonstrated that the value of Niacor-SR and the other pharmaceutical products was not $60 million

a. Dr. Levy's criticism of the terms of the license fees

290. Dr. Levy did not prove that the terms of the deal were "grossly excessive" because he performed no quantitative analysis of the value of Niacor-SR. (See Levy, Tr. 2055-64). Dr. Levy rejected the standard practice of using discounted cash flows to determine the value of a drug such as Niacor-SR. (Levy, Tr. 2059). As a result, Dr. Levy could not provide testimony as to the value of Niacor-SR – he admitted he could not testify whether a license for Niacor-SR was worth zero, $10 million or $100 million. (Levy, Tr. 2063).

291. Dr. Levy conceded that he had done no quantitative analysis of Niacor-SR. (Levy, Tr. 2057-59). Dr. Levy rejected using net present value ("NPV") analysis to value license opportunities for late stage pharmaceutical products. (Levy, Tr. 2155). He described conducting NPV analysis to determine the value of a pharmaceutical drug as "guesswork" because he believed that one "does not have a clue" as to what the risk factor is and testified that "nobody is going to rely" on such NPV calculations. (Levy, Tr. 2155-57). He testified that an NPV analysis of a late-stage pharmaceutical product that was not on the market was "GIGO," which he explained meant "Garbage in, garbage out." (Levy, Tr. 2157).

292. Other witnesses who testified in relation to NPV analysis confirmed its utility in valuing licenses, including Complaint Counsel's own witnesses. Dr. Max Bazerman,

Complaint Counsel's expert witness, testified that in his 15 years of meetings with pharmaceutical executives, none have ever expressed the view that "discounted cash flows are junk or garbage or worthless or words to that effect." (Bazerman, Tr. 8555). Complaint Counsel's expert Professor Bresnahan confirmed that NPV determinations are used to value a stream of payments and that NPV analysis is a common concept in economics and finance. (Bresnahan, Tr. 662). Upsher-Smith's expert Dr. William Kerr testified that NPV analysis is "the most common method for valuing intellectual property." (Kerr, Tr. 6277-78). Schering's expert Dr. Zola Horovitz explained that the purpose of a net present value analysis calculation is to determine what a project will return as far as profits and cash flow to a company. (Horovitz, Tr. 3615). Horovitz testified that he conducted an NPV analysis based on the information Upsher-Smith provided to Schering and concluded that Schering could have paid up to $100 million for the Niacor-SR license. (Horovitz, Tr. 3612-13).

293. Not only did Dr. Levy not perform a financial evaluation of Niacor-SR, he did not do a financial evaluation of any of the five other products licensed to Schering. (Levy, Tr. 2059). Dr. Levy admitted that he did not know as to each of the five other products licensed under the June 17 Agreement whether each product was worth zero, $10 million or $100 million. (Levy, Tr. 2062-63). Dr. Bresnahan concedes that each of these 5 other products had value for Schering. (Bresnahan, Tr. 951, 953, 956).

294. Dr. Levy admitted that he also did not do any valuation analysis on the production or supply rights for the six licensed products that Upsher-Smith granted to Schering in Paragraphs 7-10 of the license agreement. (Levy, Tr. 2059-63). In fact, Dr. Levy was unaware that Schering had received any production rights from Upsher-Smith under the agreement. (Levy, Tr. 2059-60).

295. Dr. Kerr, Upsher-Smith's valuation expert, performed a valuation of the drugs licensed in the June 17 Agreement other than Niacor-SR and determined that they were worth $10.1 million as of June 1997. (Kerr, Tr. 6300-02).

296. Instead of offering an opinion on the value of the license fees, Dr. Levy testified only that the fees were "grossly excessive." This conclusion was based in part on his belief that the $60 million up-front payment was larger than any previous license fee in the history of the pharmaceutical industry. (Levy, Tr. 1329-30). A comparison of the payment terms of various deals requires more than an isolated consideration of the up-front license fees. In performing his up-front-payments-only analysis, Dr. Levy ignored provisions relating to how the parties agreed to split future revenues generated from the product and ignored Schering's consideration of its costs to bring the product to market. (Levy, Tr. 1337, [Tr. 1464-66]; CX 1604).

297. [redacted redacted] (Levy, Tr. 1329; SPX92 at SP 00195). [redacted redacted redacted] (Levy, Tr. 1329). [redacted redacted redacted] [(Lauda, Tr. 4595; CX1402 at SP 074847)], [redacted redacted] [(CX1468 at SP 074431-32)], [redacted redacted] [(CX 1468 at SP 074433)]. [redacted redacted] [(Lauda, Tr. 4450-51)], [redacted redacted [(CX 1397 at SP 06958)]. [redacted]

298. As noted by Mr. James Egan, Complaint Counsel's rebuttal witness from Searle Pharmaceuticals, there is risk involved in making a large up-front payment (Egan, Tr. 7983). [redacted redacted redacted redacted] [(CX 1338 at SPCIDZID 12723)]. redacted redacted] [(Lauda, Tr. 4512-13)], [redacted]. [redacted redacted]. [(Lauda, Tr. 4599-4601)].

299. In evaluating a licensing opportunity, Schering analyzes the total investment required to bring a product "to a state of registration," which includes (1) research and development expenditures required to bring a product to the

approvable stage; and (2) payments that are contingent upon pre-approval events, such as successful completion of phase II studies. (Lauda, Tr. 4365- 66). With the results of the Phase III clinical trials already in Schering's hands, Niacor-SR was much further along in development than most of the other Schering deals analyzed by Dr. Levy. [(Levy, Tr. 1464-65)]; CX 1604; [(Lauda, Tr. 4405, 4468)]; SPX 2267; Horovitz, Tr. 3766). [redacted redacted redacted redacted] [(Lauda, Tr. 4465-68)]; (SPX 2264).

300. Schering also regularly considers economic value when considering an in-licensing opportunity. (Lauda, Tr. 4361-63). The economic value is the estimated economic return Schering expects to realize on a project. (Lauda, Tr. 4362). [redacted redacted redacted] [(Lauda, Tr. 4450-51)], [redacted redacted redacted] [(Lauda, Tr. 4479, 4481, 4483); CX 1397)], [redacted redacted] [(Lauda, Tr. 4478-79)]. [redacted redacted redacted redacted]. [(CX 1397 at SP 06958)] (SPX 92 at SP 00195). [(Lauda, Tr. 4481- 83)]; (19 Tr. 4479-83; CX 1397 at SP 069948).

ii. Dr. Levy's criticism of Schering's due diligence

301. Dr. Levy testified that, in his opinion, the level of due diligence performed by Schering for Niacor-SR was "strikingly superficial." (Levy, Tr. 1341-42; CX 1597). In explaining how he reached this conclusion, Dr. Levy testified that he had put himself in Schering's position in June 1997 to "try to ascertain what I might have done had I seen what they saw." (Levy, Tr. 1342).

302. In support of his testimony that the due diligence performed for Niacor-SR was "strikingly superficial," Dr. Levy compared the volume of due diligence for Niacor-SR to the volume of due diligence from two other Schering evaluations. [(Levy, Tr. 1376-78, 1492, 1516, 1886-87)]. In

selecting his two yardsticks, Dr. Levy concedes that he simply selected these comparators from a "list," and that he did not review "in toto" all 33 license evaluations for which Schering produced documents to Complaint Counsel. [(Levy, Tr. 1377, 1524)].

303. Aside from his general criticism of the volume of due diligence performed for Niacor-SR, Dr. Levy identified two specific aspects of due diligence that he believes should have raised concerns for Schering: (1) dietary supplement forms of sustained release niacin had been associated with liver toxicity; and (2) the FDA had requested that Upsher-Smith perform an additional 17-day, single-dose pharmacokinetic ("PK") study in 30 patients. (Levy, Tr. 1317, 1388; Halvorsen, Tr. 4001-03; SPX 0331). However, the liver toxicity issue had already been specifically evaluated by Schering. (Audibert, Tr. 4119-22). Also, Dr. Levy described the requirement of a PK study as follows: "Doing a pharmacokinetic study in Schering-Plough is like falling off a log. I mean they do them routinely." (Levy, Tr. 1388). Lauda testified that the PK study was, at best, a very minor issue that would not even have "caused a blip on the radar." (Lauda, Tr. 4516-17, 4421). Moreover, at the time of the license agreement for Niacor-SR, Upsher-Smith had already built the PK study into the December 1997 NDA filing timetable upon which Schering relied. (Horovitz, Tr. 3728, 3793-94).

304. The amount of due diligence that Schering performs in evaluating a licensing opportunity depends on the nature of the opportunity. (Russo, Tr. 3432-33; [Lauda, Tr. 4574]). Schering does not use any standard approach in evaluating a licensing opportunity. (Russo, Tr. 3432-33). Generally, the higher the risk involved with a particular product, the more involved Schering's review process will be. (Russo, Tr. 3432-33).

305. Unlike other products Schering has evaluated, Niacor-SR was a very straightforward product in a market with which

Schering was intimately familiar. [(Lauda, Tr. 4599-4601)]; Audibert, Tr. 4093-98, [4299-4304], 4137). Niacor-SR was a late stage Phase III product, and Schering was able to conduct its evaluation on the basis of the results of the Phase III pivotal trials. (Audibert, Tr. 4113-14; [Lauda, Tr. 4599-4600]; Horovitz, Tr. 3682, 3717; CX 1042). Niacor-SR's active ingredient, niacin, is an old and well-known compound with an established product profile. (Audibert, Tr. 4137-38; [Lauda, Tr. 4599- 4600]; Horovitz, Tr. 3681). Niacor-SR had "proof of principle" in that niacin has long been known to be effective in the treatment of high cholesterol, the exact indication targeted for Niacor-SR. (Audibert, Tr. 4116-17; [Lauda, Tr. 4599-4600]. In fact, as a result of niacin's known efficacy profile, the FDA had advised Upsher-Smith during the development of Niacor-SR that "there is no question that niacin is effective," and that "efficacy was considered almost a non-issue." (CX 1376 at Upsher-Smith FTC 127098; CX 1371). On the basis of these considerations, Dr. Horovitz testified that in evaluating a drug like Niacor-SR, he would expect that a knowledgeable person could perform the requisite due diligence more quickly than would be the case with other licensing evaluations. (Horovitz, Tr. 3682).

306. Audibert was already familiar with cholesterol lowering drugs - including niacin - as a result of his detailed evaluation of the cholesterol lowering market as part of his work on Schering's blockbuster pipeline drug, ezelimibe. (Audibert, Tr. 4095-4100). Niacor-SR was a known drug reformulated using sustained release technology to overcome a known side effect, a method of development with which Audibert had gained substantial expertise throughout his career. (Audibert, Tr. 4082-89; Horovitz, Tr. 3679-80). Audibert knew from his evaluation of Kos' Niaspan just months earlier that the FDA was on the verge of approving another sustained release niacin, and the results of the pivotal trials for Niacor-SR confirmed that Upsher-Smith had similarly succeeded in

developing a safe and effective sustained release niacin. (Audibert, Tr. 2453- 54 (Audibert Dep.); [Lauda. Tr. 4512-13]; Horovitz, Tr. 3679-80).

307. Based on Audibert's evaluation of Niacor-SR, Schering did not believe that additional due diligence was required. [(Lauda, Tr. 4516]; Audibert, Tr. 4137).

308. Dr. Levy was unfamiliar with the National Cholesterol Education Program ("NCEP"), which sets the nationally accepted guidelines for cholesterol lowering in the United States and which were relied on throughout the Kos and Upsher-Smith niacin research documents and studies. (Levy, Tr. 8404-05). Dr. Levy also demonstrated his unfamiliarity with the leading studies relating to niacin. (Levy, Tr. 8401-03, 8406).

309. Dr. Levy was mistaken in both his expert report and his trial testimony as to the type of PK study Upsher-Smith needed to complete to get its NDA for Niacor-SR approved – he was under the misimpression that a multiple dose PK study was required. In fact, by March 1997 the FDA had confirmed that Upsher-Smith only had to perform a single-dose PK study. (Levy, Tr. 2182-83; CX 917 at 107426; USX 281).

310. Dr. Levy admitted that he had not seen (and therefore had not considered) the 200-plus page final methods validation report for the Niacor-SR PK test that the CRO had been developing between summer 1997 and fall of 1998. (Levy, Tr. 2131; SPX 333 (methods validation report); Halvorsen, Tr. 3943-45 (describing MDS Harris work on report); USX 556 (December product update cited by Levy stating "MDS Harris will complete work through method validation")).

311. At the time he testified, Dr. Levy believed Upsher-Smith had only conducted the two Phase III pivotal clinical studies and was unaware that Upsher-Smith had also conducted the two longer term follow-on Phase III studies, the 900837 and the 920944 studies. (Levy, Tr. 2079-80).

312. When asked whether he took into account any follow-on studies, Dr. Levy indicated he had focused on the materials provided to Schering and believed he knew what Schering knew at the time about the status of Upsher-Smith's clinical studies. (Levy, Tr. 2079-80). However, all four clinical studies are referenced in the confidential presentation Upsher-Smith provided to Schering -- including the two follow-on studies -- and the presentation indicated that Upsher-Smith had completed or was completing the final study reports for all four. (CX 1042 at 0079). Dr. Levy conceded on cross-examination that all four reports were referenced in the materials Schering received. (Levy, Tr. 1830-31).

313. In his expert report, Dr. Levy stated that the elevated liver enzyme levels indicated in the package Schering received from Upsher Smith "would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination, in my opinion, would have included at least: Examination of liver biopsies in patients treated with Niacor-SR ..." (Levy, Tr. 1785-99). A liver biopsy is performed by inserting through the skin of the subject a seven-inch hollow needle, approximately 18-gauge, with a bore on the point that fills the bore of the needle. (Levy, Tr. 1785-99). The needle is pushed through into the liver, a chunk of the liver is removed using suction, and then the needle is removed. (Levy, Tr. 1795-96).

314. To perform such liver biopsies, Upsher-Smith would have been required to track down patients who had completed the study years earlier and re-dose those patients in an attempt to replicate those elevations, and then perform a surgical procedure to remove a piece of the patients' livers to determine whether that re-dosing had caused liver damage. (Levy, Tr. 1786-87, 1796-97). Dr. Levy testified at his deposition that it would have been "quite reasonable" for Schering to ask Upsher-Smith to do this. (Levy, Tr. 1786-87). During cross-

examination, however, Dr. Levy admitted that he "probably overstated" the opinion expressed in his expert report and deposition testimony regarding the requirement of liver biopsies. (Levy, Tr. 1790, 1793, 1798-99). Dr. Horovitz explained his experience with the clinical trials for one of the statins where a Japanese company had inquired about the possibility of taking liver biopsies of patients during the clinical trials, and the FDA considered that request "ridiculous." (Horovitz, Tr. 3708).

iii. Dr. Levy's criticism of the post deal conduct

315. Dr. Levy testified that his opinion that the "$60 million was not for Niacor-SR" rests in part on the fact that after the June 17, 1997 licensing transaction neither party showed any serious interest in marketing Niacor-SR. (Levy, Tr. 1822-23). In his report, Dr. Levy wrote that there were almost no communications between Schering and Upsher-Smith after the execution of the agreement. (Levy, Tr. 2079-80).

316. Levy's conclusion in his report and testimony that there were almost no communications between Schering and Upsher-Smith following the June 17, 1997 Agreement is contrary to the record evidence. (Levy, Tr. 2079-80). There were no fewer than 2 meetings and 21 other documented communications between Schering and Upsher-Smith in 1997 after Upsher-Smith and Schering's licensing agreement and the record indicates it is likely there were other undocumented telephone calls. The communications continued into 1998. (F. 262- 65).

317. Dr. Levy admitted that in reaching his opinion regarding Upsher-Smith's post-June 1997 efforts on Niacor-SR, he had not reviewed any of the more-than 80 minutes and agendas documenting the more-than 40 teleconferences

Upsher-Smith had held with the CROs between June of 1997 and May of 1998 contained in USX 1178 through USX 1266. (Levy, Tr. 2099-2102, 2127). Those minutes detail the ongoing work being done by Upsher-Smith and the CROs to finalize the individual study reports, to compile the ISS/ISE and to wrap up the project.(Levy, Tr. 2099-2102, 2127). Those ClinTrials teleconference minutes and agenda- memorialize that in December of 1997, Upsher-Smith had informed ClinTrials that Upsher-Smith was not going forward with filing the NDA, but that its European partner (Schering) might be proceeding. (USX 1259 at 093868; USX 1260 at 093790).

318. Based on the mistaken belief that Upsher-Smith had stopped its clinical work on Niacor-SR, Dr. Levy testified it was his belief that the Upsher-Smith went almost a year without telling Schering that Upsher-Smith had decided not to pursue its U.S. submission -- a decision Dr. Levy found "inconceivable." (Levy, Tr. 1394). Dr. Levy admitted, however, that he had been unaware of the ClinTrials documents indicating not only that Upsher-Smith had continued the clinical work into May of 1998, but that Upsher-Smith understood in March of 1998 that Schering was not going forward with its European submission. (Levy, Tr. 2099-2102, 2127; USX 1259 at 093868; USX 1260 at 093790).

b. Professor Bresnahan

319. Complaint Counsel offered the testimony of Professor Timothy Bresnahan, Professor of Economics. Bresnahan did not perform an economic valuation of any of the drugs licensed from Upsher-Smith to Schering. (Bresnahan, Tr. 950-57). He did not do a valuation analysis of Niacor-SR, pentoxifylline, Prevalite, the Klor Con products, or the supply agreement. (Bresnahan, Tr. 950-57). Professor Bresnahan also did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of $225 - 265

million presented to Schering's Board of Directors. (Bresnahan, Tr. 975-78). Instead, Bresnahan utilized a "revealed preference" test and a market test to opine on the value of Niacor-SR. (F. 320-22).

i. The "revealed preference" test

320. Professor Bresnahan applied the "revealed preference" test to opine that the $60 million payment was not for the Niacor license. Professor Bresnahan's opinion was that Schering's decision not to pay Kos for the right to co-market Niaspan revealed that Schering would not pay $60 million for a license for any sustained-release niacin product. (Bresnahan, Tr. 582, 596-98; CX 1578).

321. Schering's decision to discontinue discussions with Kos with respect to a potential co-marketing arrangement was made for reasons that did not apply to its license transaction with Upsher-Smith. First, Schering was to receive at most half the profits from sales of Niaspan. As Professor Bresnahan conceded, this meant that the projected NPV of Schering's interest in Niaspan profits was $127 million. (Bresnahan, Tr. 1115-16; CX 558; Russo, Tr. 3529-30). On the other hand, Schering was to receive all of the Niacor-SR sales after deducting a small royalty. (Levy, Tr. 1329; SPX 92 at SP 00195). As Professor Bresnahan conceded, the projected NPV of Schering's interest in the Niacor-SR sales was $225-$265 million. (Bresnahan, Tr. 1117; [Lauda, Tr. 4478-79]; SPX 26 at SP 16 00275). Second, Kos' demands from a co-promotion arrangement were high. Kos insisted that under any arrangement Schering would have to guarantee a significant number of primary details for Niaspan. (Patel, Tr. 7531, 7554; CX 769). Kos also wanted guarantees with respect to the level of sales call activity. (Russo, Tr. 3451). Third, Kos wanted to retain most of the control over how the product was marketed. (Bresnahan, Tr. 1112). Fourth, Kos insisted on booking sales

or making Schering pay money in order to book sales. (Patel, Tr. 7556). And fifth, the Kos people were proving to be very difficult to work with. (Bresnahan, Tr. 1122).

322. The substantial, reliable evidence presented by Schering demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. (F. 217-19). This evidence refutes the conclusion Professor Bresnahan reached using his "revealed preference" test. (F. 320-21).

ii. The market test

323. Professor Bresnahan testified that he applied a "market test" to prove that the $60 million was a payment for delay, and not for Niacor-SR. Professor Bresnahan's theory was that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, the "market test of the $60 million payment is failed." (Bresnahan, Tr. 601-02). Bresnahan's conclusion that the Niacor-SR license was not worth $60 million was based on his application of this "market test."

324. Professor Bresnahan had never before applied this market test in the context of pharmaceutical licensing, and he did not understand, when he applied it, how Schering normally goes about deciding what to pay for a license. (Bresnahan, Tr. 1125). When applying his market test, Professor Bresnahan did not know whether Schering customarily knew or cared what other companies were bidding for a product. Lauda explained, there is never a "market price" for a licensing opportunity. Schering generally does not know what other companies are bidding, and Schering's determination of how large a bid to make is driven by the company's own internal assessments. (Lauda, Tr. 4374-75). Complaint Counsel's rebuttal witness, Egan, (Searle) testified that one company may value a licensing opportunity differently from another. (Egan, Tr. 7964). These

differences in valuation are attributable to varying subjective criteria. (Egan. Tr. 7964).

325. During the 30 days preceding Schering's license of Niacor-SR, Upsher-Smith had received expressions of interest from a number of European companies. (Halvorsen, Tr. 3970-73). At the conclusions of the June meetings in Europe, those companies indicated that they would review Niacor-SR and contact Upsher-Smith, but not within the following month. (Halvorsen, Tr. 3974).

326. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR licence. (F. 243-57). The evidence presented by Schering that Niacor-SR was worth $60 million to Schering in June 1997 refutes the conclusion Professor Bresnahan reached using his market test.

H. ESI's Micro-K20 and Patent Litigation

1. ESI's ANDA and the initiation of patent litigation

327. In 1995, ESI Lederle, Incorporated ("ESI"), a division of American Home Products ("AHP") sought approval from the FDA to market Micro-K20, a generic version of Schering's sustained release potassium chloride tablet, K-Dur 20. (SPX 678; Miller, Tr. 3320). On December 22, 1995, ESI submitted an ANDA to the FDA that referenced K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. (Schering Answer ¶ 51; AHP Answer ¶ 51).

328. On December 29, 1995, ESI notified Schering of its Paragraph IV certification containing data from a bioequivalent study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20 tablets. (CX 419 at SP 06 00052; Schering Answer ¶ 51). The notification letter stated that the '743 patent would not be infringed by the AHP generic product since it "[did] not

contain potassium chloride crystals coated with a mixture of ethylcellulose and hydropropylcellulose or with a mixture of ethylcellulose and polyethylene glycol, as disclosed and claimed in U.S. Patent 4,863,743." (CX 419 at SP 06 00052; SPX 678 at 1).

329. On February 16, 1996, within 45 days of receiving this letter, Schering's Key Pharmaceuticals division sued ESI for "willful and deliberate" infringement of the '743 patent, as contemplated under 21 U.S.C. § 355(j)(5)(B)(iii). (Miller, Tr. 3319-20). Schering sought an injunction in the U.S. District Court for the Eastern District of Pennsylvania that would have prevented ESI from marketing its generic version of K-Dur 20 for the remaining life of the '743 patent. (Miller, Tr. 3319-21; SPX 679).

330. ESI filed an answer and counterclaim for a declaratory judgment, alleging non-infringement and invalidity of the '743 patent. (SPX 680).

331. No evidence or testimony was offered to show that Schering's filing of the patent litigation against ESI was not initiated for the legitimate purpose of defending its patent.

2. Settlement Negotiations

332. The parties first began discussing a possible settlement of the case in October 1996. (Herman, Tr. 2487). At a status conference, the presiding judge, Judge DuBois, suggested that the parties participate in a mediation session with a U.S. magistrate judge. (Herman, Tr. 2487). On October 16, 1996, both Key and ESI agreed to participate in mediation. (Herman, Tr. 2495; SPX 73). The magistrate judge appointed to participate in the mediation was Judge Rueter. (Herman, Tr. 2486). The mediation process with Judge Rueter ultimately lasted approximately 15 months. (Herman, Tr. 2486).

333. Throughout the course of the litigation between Schering and ESI, Judge DuBois made it clear that he wanted the parties to settle the case. (SPX 1222 at 53:13-25 (Alaburda I.H.)). Judge DuBois brought up settlement every time be talked to the parties, usually as the first order of business. (SPX 1222 at 73:3-16 (Alaburda I.H.)).

334. The parties participated in a settlement conference on November 19, 1996 in Judge Rueter's chambers. (Herman, Tr. 2497; SPX 77).

335. On December 10, 1996, Schering proposed to ESI that they enter into a co-promotion venture in which Schering and ESI would jointly fund and manage a third-party workforce in marketing K-Dur 20. (Herman, Tr. 2503-04; CX 1482 at 67 (Alaburda I.H.); CX 1494 at 101 (Driscoll I.H.); SPX 76).

336. ESI rejected the proposal on February 20, 1997, stating that, as a generic manufacturer, ESI did not have a sales and detail force capable of selling and marketing K-Dur 20. (Herman, Tr. 2504; CX 1482 at 70 (Alaburda I.H.); CX 1492 at 56 (Dey I.H.); CX 457).

337. Eight days later, on February 28, 1997, another mediation session took place in Judge Rueter's chambers. (Herman, Tr. 2504; SPX 1202).

338. Following the February 1997 mediation session, the parties continued to discuss settlement proposals. On March 12, 1997, Judge DuBois sent a letter to counsel stating that he understood from Judge Rueter that settlement negotiations were continuing, and expressing his hope that the parties would settle. (Herman, Tr. 2513; SPX 1198).

339. On March 19, 1997, Mr. Paul Heller, ESI's outside counsel, wrote Mr. Anthony Herman, Schering's outside counsel, a letter stating that he had been advised that Schering's copromote proposal "raises considerable antitrust risks." (Herman, Tr. 2513; CX 458). The letter noted, again, that ESI was amenable to an arrangement whereby Schering would pay ESI and ESI would receive a license to enter the market in the

future. (Hoffman, Tr. 2659-60; CX 458). Schering explained to ESI that this proposal was unacceptable. (Hoffman, Tr. 2631-32).

340. On April 18, 1997, Herman sent a letter to Judge Rueter on behalf of both Schering and ESI reporting on the state of the settlement efforts as being at"a standstill." (Herman, Tr. 2514; CX 459; CX 1492 at 129 (Dey I.H.)).

341. On August 20, 1997, Judge Rueter held a third mediation session in his chambers. (Herman, Tr. 2515; SPX 552).

342. Following the August 20, 1997 mediation session, on September 24, 1997. Heller sent a letter to Herman. (Herman, Tr. 2519; SPX 94). That letter projected the amount of profits that ESI believed it would earn if it were to win the case. (Herman, Tr. 2519; SPX 94, at SP 13 00004). ESI projected that, with the simultaneous launch of three generic versions of K-Dur 20, ESI's generic would earn over $15 million in sales in the first year on the market. (SPX 94, at SP 13 00004). ESI projected that its generic version of K-Dur 20 would earn over $25 million in sales in its second year on the market, over $28 million in its third year on the market, over $24 million in its fourth year on the market, and over $23 million in its fifth year on the market. (SPX 94, at SP 13 00004).

343. Schering was willing to discuss other opportunities that were mutually beneficial to the parties apart from an outright payment to ESI. (Kapur, Tr. 1431; SPX 1242 at 125-27 (Kapur Dep.)). Mr. Martin Driscoll, then Vice President of Marketing and Sales for Key, discussed several such opportunities with ESI, including co-marketing Schering's products. (CX 1510 at 140 (Kapur I.H.); Kapur, Tr. 1431).

344. On October 14, 1997, Dr. Michael Dey, CEO of ESI, wrote a letter to Kapur, the head of Schering's generic division, to discuss a proposal for ESI to license several products to Warrick for overseas sale. (Herman, Tr. 2519; CX 465; CX 1482 at 121-24 (Alaburda (I.H.)). Those two products were

enalapril and buspirone. (Herman, Tr. 2519-20; CX 1482 at 122-23 (Alaburda I.H.); SPX 1242 at 125-27 (Kapur Dep.)).

345. The next mediation session occurred on October 27, 1997 in Judge Rueter's chambers. (Herman, Tr. 2520). No settlement between the parties was reached that session. (Hoffman, Tr. 2618; Herman, Tr. 2520).

346. Another settlement conference was scheduled for November 17, 1997. (CX 468). On November 12, 1997, Herman sent Judge Rueter a letter expressing Schering's position that it would be a waste of the Court's and the parties' time to proceed with the scheduled settlement conference. (Herman, Tr. 2521; CX 468). At that point, ESI had told Schering that it was no longer interested in a co-promotion arrangement. (Herman, Tr. 2522; CX 468). This was the last time the copromote concept was raised. (Herman, Tr. 2522). The letter informed Judge Rueter that ESI had stated it was unwilling to agree to Schering's copromote proposal because of antitrust concerns. (Herman, Tr. 2522; CX 468). ESI responded that although ESI was not interested in a co-promote, the parties were considering separate licensing opportunities. (SPX 1195).

347. Herman's letter also addressed Schering's concerns that ESI lacked a potentially marketable product, informing Judge Rueter that Schering was unwilling to make another settlement offer until ESI demonstrated that it has a bona fide 20 milliequivalent potassium chloride product that, but for the lawsuit, would receive FDA approval. (Herman, Tr. 2522; CX 468).

348. The proposed November 17, 1997 settlement conference was postponed. (Herman, Tr. 2521).

349. ESI then provided Schering with information related to the current FDA approval status of ESI's proposed generic version of K-Dur. (Herman, Tr. 2523; SPX 82). On December 15, 1997, Mr. Herman summarized this information in a letter to ESI's counsel. Mr. Herman's December 15, 1997 summary

noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version of K-Dur 20. The main problem ESI had involved a study included in the ANDA designed to demonstrate ESI's proposed generic was bioequivalent to K-Dur 20. (CX 469; Herman, Tr. 2523). The bioequivalence study had been performed in 1989. (CX 469; Herman, Tr. 2523-24). The FDA found five different deficiencies with regard to the study. (CX 469; Herman, Tr. 2523-24). ESI did not respond to the FDA regarding the deficiencies until May 14, 1997. (CX 469; Herman, Tr. 2524). On August 6, 1997, FDA rejected ESI's response to the five deficiencies in ESI's bioequivalence study. (CX 469; Herman, Tr. 2524). ESI began a new bioequivalence study on December 8, 1997, a week before the December 15, 1997 summary. (CX 469; Herman, Tr. 2524).

350. Two days later, in a December 17, 1997 letter from Schering to ESI, Schering proposed to settle the lawsuit by providing ESI with a license to market ESI's proposed generic version of K-Dur, effective December 31, 2003. (Hoffman, Tr. 2638-39; Herman, Tr. 2525; CX 470).

351. The December 17, 1997 letter stated:

> We propose to settle the case based on the following:
> (1) Schering shall grant ESI a royalty-free license under the '743 patent to make, use, offer for sale and sell its Micro-K 20 potassium chloride product in the United States effective December 31, 2003. Until that date, ESI shall not make, use, offer for sale or sell its micro-K product.
> (2) ESI will acknowledge infringement and validity of the '743 patent in a consent judgment.

(CX 470; Herman, Tr. 2525-26).

352. In the same December 17, 1997 letter, Schering also proposed that:

> As an additional matter, ESI shall grant Schering, including its designee, exclusive licenses for buspirone, enalapril, and three other products under development by ESI to be mutually agreed upon by the parties .... In exchange for the licenses described in the unnumbered paragraph above, Schering shall pay ESI an up-front payment of $5 million and a 5 percent royalty on annual sales for ten years post-approval.

(CX 470; Herman, Tr. 2526).

353. ESI responded to Schering's offer on December 22, 1997, accepting the December 31, 2003 entry date:

> The general structure of your December 17 proposal is acceptable with the following modifications. The effective date of the license under the '743 patent should be December 31, 2003, or whenever a generic is placed on the market, whichever occurs earlier .... ESI will be able to market in the United States if the '743 Patent is invalidated or rendered unenforceable by another party.

(CX 473; Herman, Tr. 2527; Hoffman, Tr. 2639). ESI also agreed to acknowledge validity and enforceability of the '743 patent, but would not acknowledge that its product infringed. (Herman, Tr. 2528; CX 473).

354. The date of December 31, 2003 referred to in the letters differs from the date for ESI's product entry in the final agreement by one day. (Herman, Tr. 2525; CX 470; CX 473; CX 479). In the final agreement, the date agreed upon for ESI's product entry was January 1, 2004. (Herman, Tr. 2525; CX 479).

355. ESI also agreed, in its December 22, 1997 letter, to grant licenses to Schering for buspirone, enalapril, and three other products to be agreed upon. (Herman, Tr. 2528; CX 473;

CX 1509 at 70 (Hoffman Dep.)). ESI countered with an initial $5 million payment, to be followed by further payments upon the FDA's issuance of an approval letter for ESI's ANDA and thereafter for a total of $55 million on an agreed-upon time schedule. (Hoffman, Tr. 2528; CX 473). This represents a $50 million difference from Schering's offer. (Herman, Tr. 2528; CX 470; CX 473). ESI also proposed a royalty rate of 50 percent of gross profit for the licenses to Schering, as opposed to Schering's proposal of 5 percent of annual sales. (Herman, Tr. 2528.29; CX 473; CX 470).

3. Settlement agreement in principle

356. Between the time of the December 22, 1997 correspondence and January 23, 1998, the date Schering and ESI reached an agreement in principle, Schering and ESI had agreed on a January 1, 2004 date of entry for ESI. (Hoffman, Tr. 2640, 2619-20, 2638; CX 1509 at 70 (Hoffman Dep.); Herman, Tr. 2532-33). Schering told ESI that January 1, 2004 was as far as Schering would go. (CX 1482 at 99- 100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.); CX 1492 at 136-37 (Dey I.H.)). Schering made it very clear to ESI that "that was it. That was as far as they would go, and there wouldn't be any further negotiating on that point." (CX 1482 at 99-100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.)).

357. The final mediation sessions occurred on January 22 and 23, 1998, in conjunction with a Markman hearing held on January 21 and 22, 1998. (Herman, Tr. 2529). A Markman hearing is a hearing at which evidence is taken and argument is heard so that the Court can interpret the claims of the patent at issue in the lawsuit. (Herman, Tr. 2529).

358. On January 22, 1998, the second day of the Markman hearing, the Court finished hearing evidence at around 1 p.m. (SPX 687, at ESI HRG 000126-27). The parties had another settlement conference with Judge Rueter scheduled for 2 p.m.

(SPX 687, at ESI HRG 000126-27). The parties spent about three and a half hours in the January 22, 1998 settlement conference with Judge Rueter. (SPX 687, at ESI HRG 000128).

359. On January 23, 1998, the parties had another settlement conference with Judge Rueter. (Herman, Tr. 2529). The session concluded about 11:30 p.m., when an agreement in principle was reached. (Herman, Tr. 2529, 2531-32).

360. At the January 23, 1998 meeting, for Schering, were Mr. Herman and Ms. Susan Lee, Director of Patent Litigation. For ESI, were Mr. Heller and Dr. Dey. (Herman, Tr. 2532). During the evening, there were also calls between Judge Rueter and John Hoffman of Schering, who was at home, and between Judge Rueter and Mr. Driscoll, who was on his cellular phone at a New Jersey Nets basketball game with his sons. (Hoffman, Tr. 2603, 2618-19; 2629; Herman, Tr. 2532; Driscoll, Tr. 2706).

361. Before the January 23, 1998 mediation conference, the date of market entry for ESI's generic product had been agreed to in principle as January 1, 2004. (Hoffman, Tr. 2640, 2619-20, 2638; Herman, Tr. 2532-33). The parties had also agreed in principle that Schering would license generic enalapril and buspirone from ESI for $15 million. (Herman, Tr. 2532; Hoffman, Tr. 2620).

362. During the meeting, ESI insisted on additional payments. (Herman, Tr. 2533). Mr. Herman took the position that Schering was not going to pay any more money, and that it wanted to try the case. (Herman, Tr. 2533). Schering eventually agreed to pay ESI $5 million to settle the case. (Hoffman, Tr. 2620; Herman, Tr. 2534). ESI continued to insist on another $10 million. (Herman, Tr. 2535).

363. Driscoll, testified that he came up with a concept under which Schering would not have to pay ESI any money if ESI could not obtain approval of its ANDA product. If ESI received approval for its ANDA by a date certain, Schering

would make a certain payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21; CX 1492 at 156-57 (Dey I.H.)). If the date was later, it would be a lesser payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21). Driscoll ultimately agreed that Schering could make certain payments, consisting of $10 million if ESI's ANDA were approved by July, $5 million if it were approved 6 months later, with further decreasing payments. (Driscoll, Tr. 2712).

364. When Driscoll made this commitment, he believed that Schering would not have to pay it. (Driscoll, Tr. 2713, 2722; CX 1509 at 104 (Hoffman Dep.); CX 1482 at 109 (Alaburda I.H.)).

365. Judge Rueter asked the parties to write up the terms and initial or sign them that night. (Hoffman, Tr. 2621). In the secretarial area of Judge Rueter's chambers, Heller, counsel for ESI, hand wrote out the settlement principles with Schering's representatives. (Herman, Tr. 2537, 2488; CX 472).

366. The two-page handwritten agreement in principle, dated January 23, 1998, was signed by Mr. Heller, for ESI, and for Key by Ms. Susan Lee, who was the director of patent litigation for Schering. (Herman, Tr. 2488-89; CX 472).

367. The January 23, 1998 handwritten agreement in principle states that Schering would grant ESI a license under its K-Dur patent beginning on January 1, 2004. (CX 472).

368. The January 23, 1998 handwritten agreement, states that ESI grants to Schering the right to market ESI's generic versions of enalapril and buspirone in Europe. (CX 472). The handwritten agreement also states that Schering would provide $10 million to ESI upon the signing of the settlement agreement, and $10 million split into equal monthly installments to be paid over seven and a half years. (CX 472). In addition, the handwritten agreement states that Schering would pay ESI an amount between $625,000 and $10 million,

depending on the date of FDA approval of ESI's generic version of K-Dur 20. (CX 472).

369. Immediately after the agreement in principle was reached on January 23, 1998, the district judge conditionally dismissed the case. (Hoffman, Tr. 2651- 52).

4. Final settlement agreement

370. Ms. Somerville, ESI's outside counsel, later sent a more formal draft agreement to Mr. Herman, accompanied by a transmittal letter. (Herman, Tr. 2538; CX 478). That initial draft does not accurately reflect what the parties agreed to that evening with Judge Rueter. (Herman, Tr. 2539; SPX 1266 at 181- 82; CX 478). Paragraph 16 of the draft characterizes all the payments as royalty payments, when only $15 million of the $30 million were royalty payments. (Herman, Tr. 2539; CX 478).

371. This error was corrected in the final drafts of the agreements. (Herman, Tr. 2539; CX 479; CX 480). The final drafts of the agreements were prepared by Schering's outside counsel, Covington & Burling. (Herman, Tr. 2539). The final agreement was reached in June 1998. (Herman, Tr. 2539; Hoffman, Tr. 2652; CX 479).

372. Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment and an additional $10 million contingent on ESI's FDA approval. (Hoffman, Tr. 2643; CX 479). Schering granted under the '743 patent a royalty free license to ESI effective, January 1, 2004. (Hoffman, Tr. 2643; CX 479).

373. The final settlement agreement also provides that Schering wishes to market in Europe certain pharmaceutical products for which ESI has filed ANDAs with the FDA. (CX 479).

374. As provided in the earlier handwritten agreement, Schering and ESI also entered into a contemporaneous license

agreement, dated June 19, 1998, whereby AHP and ESI granted to Schering the licenses to enalpril and buspirone in exchange for $15 million. The license agreement includes a statement that the parties desire to eliminate the uncertainties and costs of the patent litigation between Schering and ESI over the '743 patent. (CX 479).

375. Schering paid ESI $5 million ten days after the execution and delivery of the June 19, 1998 final settlement agreement. (Schering Answer at ¶ 59). Shortly before the June 1999, $10 million payment deadline, ESI received approval from the FDA. (Hoffman, Tr. 2646). Schering then paid ESI $10 million. (Hoffman, Tr. 2646).

5. Settlement language related to other products

376. The terms of the final settlement agreement that were added after the agreement in principle was reached included: (1) ESI could not market any potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" until January 1, 2004; (2) ESI cannot market more than one new potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" between January 1, 2004 and September 5, 2006; (3) ESI cannot conduct, sponsor, file, or support a bioequivalence study or a substitutability study of a potassium chloride product to K-Dur 10 or K-Dur 20 until Schering's patent expires in 2006; (4) if ESI acquires a business, the new business could not seek FDA approval for a potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" prior to September 5, 2006; and (5) ESI cannot transfer ESI's ANDA. (CX 479).

377. The inclusion of clauses in the settlement agreements that affected ESI's exploitation of products similar to K-Dur 20

for a period of time prevent ESI from making minor, insubstantial modifications to its product and filing another ANDA with an infringing product. (SPX 1228 at 159-60 (Dey I.H.)).

6. Complaint Counsel did not prove that Schering's payment to ESI was a payment to delay entry

378. Complaint Counsel introduced fact evidence only in the form of deposition and investigational hearing testimony of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. It offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. (Bresnahan, Tr. 618-40).

379. Professor Bresnahan testified that to reach a conclusion that the agreement between Schering and ESI delayed competition, he relied upon what he characterized as an "assumption" that if ESI had won its patent suit, it might have been able to enter before March 2002. (Bresnahan, Tr. 620-21). This unfounded opinion, based only on speculation, does not demonstrate that the patent case would have settled any earlier for any reason.

380. Complaint Counsel offered insufficient evidence to show that the $15 million was not paid for the licenses to enalapril and buspirone. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. Complaint Counsel offered insufficient evidence of what the fair value of enalapril and buspirone was.

381. Schering has made no sales from either enalapril or buspirone. (Schering Answer at ¶ 56). Schering has been pursuing registration of both enalapril and buspirone in Europe and anticipates filing for approval in 2002. (SPX 1242 at 133-35 (Kapur Dep.)).

382. A statement made in an investigational hearing by Michael Dey, an ESI official involved in the settlement negotiations, that "if Schering had been willing to allow [ESI] onto the market before 2004," ESI "may have" been willing to settle for less money is insufficient to demonstrate that Schering paid ESI only for delay or that the case would have settled sooner for any reason. (Bresnahan, Tr. 632-33 (quoting Dey I.H.)). This is not sufficient to prove payment only for delay.

383. Complaint Counsel offered insufficient evidence to demonstrate that the patent case would have settled without the provision for the product license.

384. Schering's expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. (Mnookin, Tr. 2675-76.) Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. (Mnookin, Tr. 2675-76.)

I. Whether Schering's Payments to Upsher-Smith and AHP Were for Delay

385. A patent owner is given the exclusive right to preclude others from making, selling, using or vending the subject matter of the invention covered by the claim. (35 U.S.C. § 271(a); Miller, Tr. 3310-11). To enforce a patent, the patentee is given the right to sue in a federal court for patent infringement. (35 U.S.C. § 271: 28 U.S.C. § 1338; Miller, Tr. 3316).

386. The '743 patent gives Schering the right to "exclude others from making, using, offering for sale, and selling the invention throughout the United States," together with certain additional rights provided in the statute. 35 U.S.C. § 154. The

'743 patent expires on September 5, 2006. (Miller, Tr. 3311; SPX 1275 at ¶ 8). Hence, Schering has the right to exclude infringing products from the market until September 5, 2006. (Miller, Tr. 3311).

387. An applicant who has filed an ANDA with a Paragraph IV certification must notify the branded drug manufacturer and the patent holder of the filing of its ANDA, and provide a detailed statement of the factual and legal bases for the ANDA filer's opinion that the patents will not be infringed or are invalid. (21 U.S.C. § 355 (j)(2)(B)(i) and (ii); Hoffman, Tr. 2217-18).

388. Under Hatch-Waxman, the branded drug manufacturer has 45 days after receiving such notice to file a patent infringement suit against the ANDA applicant in order to automatically trigger a stay of FDA approval of the ANDA. If a patent infringement suit is filed within this 45-day window, the FDA cannot give final approval for the ANDA until the earliest of: (1) the date the patent is judicially determined to be invalid or not infringed; (2) a judicial determination of the patent litigation, or (3) the expiration of an automatic 30-month waiting period, which may be extended or shortened by the court. (Hoffman, Tr. 2218; Rosenthal, Tr. 1575-76; 21 U.S.C. § 355 (j)(5)(B)(iii)).

389. The patent holder, if successful in proving that the generic product infringes his patent in the patent infringement litigation, can keep the ANDA from being approved and enjoin the marketing of the generic product until the patent expires. (Miller, Tr. 3316-17; Rosenthal, Tr. 1576).

390. A generic drug company could be involved in patent litigation with the patent holder, and at the end of the 30-month stay of FDA approval receive final approval from the FDA for its product, but still not enter the market given the risks of patent infringement and potential treble damages. (Rosenthal, Tr. 1578-81). There are numerous situations in which companies have not gone to market with their generic

alternatives, even though they have FDA approval, specifically out of fear of an adverse ruling in an ongoing patent infringement suit. (Rosenthal, Tr. 1582-87; Kerr, Tr. 6259-60; 6901-02).

391. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20. (Dritsas, Tr. 4902-03). Shortly before June 1999, ESI received approval from the FDA for its generic version of K-Dur 20. (Hoffman, Tr. 2646). However, it would be "Toolhardy" for a generic to enter the market while patent litigation is pending because of the potential "very, very severe penalties." Kerr, Tr. 6738. Paul Kralovec, Upsher-Smith's CFO, testified that for Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "financial suicide." (Kralovec, Tr. 5038). ("[I]f we had lost the case, it could have been significant financial obligation for us to pay as far as damages go."). Schering's lead counsel on the patent infringement case brought by Key Pharmaceuticals against ESI Lederle, Anthony Herman, a partner at the law firm of Covington & Burling, testified that in his practice he has never encountered a generic manufacturer who sought to enter the market after the 30-month stay had expired but while patent litigation was ongoing. (Herman, Tr. 2484-2568).

392. Thus, even though Upsher-Smith and ESI had final FDA approval as of November 1998 and June 1999 respectively, it is highly unlikely that either would have marketed on those dates while patent litigation was still pending. (F. 391).

393. There is no way to determine the date or the outcome of the judicial determination of the patent litigation. Schering's expert, Mr. James O'Shaughnessy, a patent trial lawyer testified that patent litigation is by its very nature unpredictable. (CCPTB at p. 71; Miller, Tr. 7065). Schering's patent expert, Mr. Charles Miller testified there is no recognized methodology

for handicapping trials or for testing the reliability of predictions of litigation outcomes. (CCPTB at p. 73; Miller, Tr. 3296). Opinions on the merits of cases that settle before the court decides them can never be tested. (CCPTB at p. 73; Miller, Tr. 3296).

394. Complaint Counsel acknowledges that the outcome of the patent litigation cannot be predicted. (CCPTB at p. 71). Complaint counsel's patent litigation expert, Professor Martin Adelman, testified that patent infringement cases can take up to five years to litigate in some federal district courts, not including appeals. (Adelman, Tr. 7773-74). Intellectual property litigation is more uncertain than other types of litigation. The Federal Circuit, which hears intellectual property appeals, has a 50 percent reversal rate, making it extremely difficult to predict the outcomes of intellectual property litigation. (O'Shaughnessy, Tr. 7065-66).

J. 180 Day Exclusivity Period

1. No firm was actually blocked from introducing a generic 20 mEq potassium chloride supplement

395. Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx testified that Andrx [redacted] (Rosenthal, Tr. 1553, 1591, 1734-35). [redacted redacted redacted] (Rosenthal, Tr. 1728-31). [redacted redacted redacted] (Rosenthal, Tr. 1735).

396. Executives at Upsher-Smith were not aware of any other potential competitors blacked from the market. (Dritsas, Tr. 4667, 4686-87; Troup, Tr. 5494-95).

397. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. (Bresnahan, Tr. 912). Despite the running of the 180-day period, Bresnahan admitted that there were

currently three generic 20 mEq potassium tablet products on the market during the period: Warrick (Schering), Klor Con M20 (Upsher-Smith), and Qualitest. (Bresnahan, Tr. 929). Bresnahan also testified that the change in law regarding 180-day exclusivity was not attributable to Upsher-Smith's or Schering's conduct. (Bresnahan, Tr. 982).

398. Complaint Counsel introduced no evidence of any competitor blocked from entry into the market because of Upsher-Smith's 180 exclusivity.

2. The 180-day period was not discussed between Schering-Plough and Upsher Smith

399. The 180-day exclusivity period was never discussed during settlement negotiations between Schering Plough and Upsher-Smith. (Troup, Tr. 5492-93; Hoffman, Tr. 3550-51). Nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. (Bresnahan, Tr. 914-17); CX 348; Troup, Tr. 5493).

K. Monopolization

1. Market share

400. In March 1995, seventy-one percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1275; CX 13 at SP 003044). In April 1996, sixty-eight percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1276-1277; CX 746, CX 18). Of total prescriptions between 1994 and 1999, the total number of K-Dur 20 prescriptions was only slightly higher than the total number of generic prescriptions, with K-Dur 20 comprising 25.7% versus the generics' 24.1% (1994); K-Dur 20's 28.4% versus the generics' 27.4% (1995);

K-Dur 20's 30.9% versus the generics' 28.9% (1996); K-Dur 20's 33.0% versus the generics' 31.1% (1997); K-Dur 20's 34.8% versus the generics' 32.7% (1998); and K-Dur 20's 35.8% versus the generics 33.6% (1999). (CX 1389 at SP 23 00016).

401. As reflected in a July 1, 1996 Schering document entitled "K-Dur Marketing Research Backgrounder," K-Dur 20 represented 32 percent of total prescriptions. (CX 746 at SP 2300382). The 1998 K-Dur Marketing Plan represents that the market share for K-Dur 20 as of August 1997 was less than 38 percent. (Bresnahan, Tr. 1279; CX 747 at SP 23 00091).

402. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. CX 62 at SP 089326 for 1997 generic KCL growth. However, at the time relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. (CX 62 at 089327). With K-Dur 20 at 33.0% of total potassium chloride prescriptions, id., other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. (Russo, Tr. 3421-2212).

403. Between 1995 and 1999, other Schering documents calculated the market share of K-Dur 20 at between 30 and 40 percent. (Bresnahan, Tr. 1169-70). No Schering documents gave Schering a 100% market share.

404. Schering's market share does not indicate that Schering had monopoly power. (Addanki, Tr. 5719, 5724, 6209; Bresnahan, Tr. 876).

2. Lack of entry barriers and the ability of rivals to expand output

405. Professor Bresnahan did not analyze entry into potassium chloride supplements by Ethex, Apothecon. ESI Lederle, Medeva or Biocraft in 1996 as part of his economic analysis in this case. (Bresnahan, Tr. 8185). Professor Bresnahan did not analyze how long it took these firms to begin selling potassium chloride. [Bresnahan, Tr. 8185-86].

406. As of 1997, there were over 30 products competing in the potassium chloride market, all of which had entered at some point. (Addanki, Tr. 5721- 22). A number of new competitors entered the market in recent years. (Addanki, Tr. 5721; Dritsas, Tr. 4715). Several companies entered the potassium chloride market in 1996, including Apothecon, ESI, Medeva and Biocraft. (Dritsas, Tr. 4717; USX 626; USL 15228). Apothecon in particular was a very low-priced competitor with a wide range of generic products, including 10 mEq potassium product. (Dritsas, Tr. 4717-18). There were at least two other products that had already been approved, K-Norm and K-Lease, that could enter the market, but which were not yet in the market. (CX 4 at 184403).

407. Firms already in the market could expand output. (Addanki, Tr. 5722-23). Apothecon's 10 mEq market grew 80 percent in 1998, which was a significant shift in sales of potassium chloride. (Addanki, Tr. 6177; CX 75 at USL 142364; CX 73 at USL 143202-03). In 1999, Ethex and Major increased their 10 mEq potassium chloride capsule sales revenue by 68.4 and 19.7 percent, respectively, and increased unit output by 56.6 and 6.1 percent, respectively. (CX 76 at 162110). Among 10 mEq wax matrix producers, K-Tab, Qualitest, Major and Apothecon increased unit sales by 17, 100, 51 and 60 percent, respectively. (CX 76 at 162109; Addanki, Tr. 6181; USL at 162109). Another product, Slow-K,

showed a unit increase of 41% from 1994 to 1995. (Addanki, Tr. 6181; USX 380).

408. Complaint Counsel presented no evidence that Schering had any ability to restrict the output of the more than 20 firms selling therapeutically equivalent potassium chloride supplements.

3. Sales of K-Dur were expanding

409. Schering's documents reflect that Schering was seeking to expand sales and to engage in advertising and promotional activities that stimulate demand for the product. (Addanki, Tr. 5744). Such activities have the effect of expanding output. (Addanki, Tr. 5744). Dr. Addanki analyzed Schering's output as part of his analysis of whether Schering had monopoly power. (Addanki, Tr. 5744).

410. Schering's sales of K-Dur 20 did expand. From 1990-1996, K-Dur 20 grew more rapidly in units than did the rest of the potassium chloride market. (CX 79 at USL 138066). Schering's sales continued to expand between 1996 and 2000. (Bresnahan, Tr. 8181). According to Professor Bresnahan, between 1997 and 2001, K-Dur output increased by one-quarter (25 percent). (Bresnahan, Tr. 8181).

411. Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and physician awareness activities. Addanki, Tr. 5726-28. Schering outspent Upsher-Smith in its marketing of Klor Con 10 by a factor of 100 to 1. (Bresnahan, Tr. 734). (CX 746 at 00384(Appendix A-5, K-Dur Marketing Research Backgrounder, July 1, 1996). This extensive advertising campaign was designed to compete against generic forms of potassium supplements. (Addanki, Tr. 5730-32).

412. Schering invested millions in promotion and field force effort, with a number of significant promotional programs over that approximate ten-year period that heavily promoted

and marketed K-Dur 10 and K-Dur 20. (Russo, Tr. 3418-19, 3425-26).

413. Schering's executives recognized that marketing was a key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039).

4. Bresnahan's conclusion that K-Dur 20 was a monopoly was not based on a thorough examination of the potassium supplement industry

414. Complaint Counsel's economic expert, Professor Bresnahan opined that Schering has monopoly power in the K-Dur 20 market. Under Professor Bresnahan's test, the issue of whether or not the June 1997 Settlement Agreement of the '743 patent infringement case was "anticompetitive" turns on the following three questions:

(1) Does the patent holder have monopoly power?
(2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
(3) Is there a payment to the potential entrant to delay its entry? The payment can take any form, as long as it is a net positive value to the entrant.

Bresnahan, Tr. 655-58.

415. The three elements of the Bresnahan Test are to be assessed as of the date the Agreement was entered into, June 17, 1997. Bresnahan, Tr. 659.

416. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. Bresnahan, Tr. 660- 661.

417. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. Bresnahan, Tr. 419 ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't wouldn't do anything to harm competition.").

418. Professor Bresnahan incorrectly determined that Schering had unlawful monopoly power. (F. 30).

419. Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for its Klor Con 10 or Klor Con 8 potassium products, or the pricing of other potassium manufacturers' potassium products because he did not have access to a data set of such pricing data for the period 1995 to 2001. (Bresnahan, Tr. 834-35).

420. Bresnahan did not calculate the pricing differential (if any) between the various firms' potassium products and the price charged by Schering for equivalent does of K-Dur 20. (Bresnahan, Tr. 1071; USX 72).

421. Bresnahan conducted no econometric analyses comparing sales of 10 mEq tablets with sales of 20 mEq tablets or comparing the sales of 20 mEq potassium powders with 20 mEq tablets. (Bresnahan, Tr. 685-89).

422. Bresnahan did not study the cross-clasticity of demand between K-Dur 20 and other products. (Bresnahan, Tr. 810-11). Bresnahan did not study the direct price elasticity between K-Dur 20 and other potassium products.

423. Bresnahan did not attempt a study of the costs of Schering's K-Dur 20 products or the relationship between Schering's costs for producing K-Dur 20 and the price Schering

charged for K-Dur 20. (Bresnahan, Tr. 834, 1274, 1003, 8148-50).

424. Bresnahan did not study the level of rebates that Schering gave back to its customers who purchased K-Dur 20 potassium products in 1995, 1996 or 1997. (Bresnahan, Tr. 702). Bresnahan conceded that there was significant promotional spending by Schering to promote its K-Dur 20 product, but he did not study this spending. (Bresnahan, Tr. 651-52, 735, 763, 1176).

425. Bresnahan did not make any formal study of the impact of Schering-Plough's marketing on the total market demand for potassium chloride products. (Bresnahan, Tr. 651-52).

426. Bresnahan did not study "first mover effects," the effects of being the first to sell a particular product of K-Dur 20. (Bresnahan, Tr. 653).

427. Bresnahan made no analysis of promotional expenditures by Schering on K-Dur 20 in his report. (Bresnahan, Tr. 734-35). But Bresnahan acknowledged that Schering outspent Micro-K in by a factor of ten to one and outspent Upsher-Smith in its marketing of Klor Con 10 by a factor of 100 to one. (Bresnahan, Tr. 734.)

428. Bresnahan had no access to monthly sales data or pricing data from any firm aside from Respondents. (Bresnahan, Tr. 867-68).

429. Bresnahan did not review any marketing documents from other potassium supplement manufacturers. (Bresnahan, Tr. 867). Bresnahan did not systematically evaluate the levels of promotional spending by other potassium supplement firms over the period 1997 to 2001, such as the manufacturers of the branded potassium products Micro-K, Slow K, K-Tab. (Bresnahan, Tr. 8134).

430. Professor Bresnahan was unaware of clinical trials that compare patient compliance attributes of taking two 10 mEq tablets versus one 20 mEq tablet.(Bresnahan, Tr. 692).

431. Bresnahan did not evaluate or analyze the fact that four firms entered the U.S. potassium chloride market in 1996. (Bresnahan, Tr. 8184-85).

III. CONCLUSIONS OF LAW AND ANALYSIS

A. Jurisdiction

The Complaint charges Schering and Upsher-Smith ("Respondents") with violations of Section 5 of the FTC Act. 15 U.S.C. § 45. Section 5 of the FTC Act gives the Commission jurisdiction to prevent unfair methods of competition by "persons, partnerships, or corporations." 15 U.S.C. § 45. Schering and Upsher-Smith are corporations engaged in the interstate sale of pharmaceutical products. F. 1-9. The Commission has jurisdiction over acts or practices "in or affecting commerce," providing that their effect on commerce is substantial. McLain v. Real Estate Bd. of New Orleans, Inc., 444 U.S. 232, 241-42 (1980); Hosp. Bldg. Co. v. Trs. of Rex Hosp., 425 U.S. 738, 745-46 (1976). Respondents' challenged activities relating to the sale of 20 mEq potassium supplements have an obvious nexus to interstate commerce. F. 1-9. Accordingly, the Commission has jurisdiction over Respondents and the subject matter of this proceeding.

B. Burden of Proof

An initial decision must be supported by "reliable, probative and substantive evidence." Commission Rule 3.51(c), 16 C.F.R. § 3.51(c)(1). "Substantial evidence is more than a mere scintilla. It means such evidence as a reasonable mind would accept as adequate to support a conclusion. It must be of such character as to afford a substantial basis of fact from which the fact in issue can be reasonably inferred. It excludes

vague, uncertain or irrelevant matter. It implies a quality and character of proof which induces conviction and makes a lasting impression on reason." Carlay Co. v. FTC, 153 F.2d 493, 496 (7th Cir. 1946).

"Counsel representing the Commission ... shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." Commission Rule 3.43(a), 16 C.F.R. § 3.43(a). This is consistent with Section 556(d) of the Administrative Procedure Act ("APA"); "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). Further, under the APA, an order may not be issued "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); see also In re Standard Oil Co. of California, 84 F.T.C. 1401, 1446-47 (1974) (finding that under the APA, "[c]omplaint counsel have failed to satisfy their burden to establish by 'reliable, probative and substantial evidence' that the results mentioned in the preceding findings do not support [respondent's] advertising claims").

"[T]he antitrust plaintiff must present evidence sufficient to carry its burden of proving that there was [an anticompetitive] agreement." Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 763 (1984). The government bears the burden of establishing a violation of antitrust law. United States v. E.I. duPont de Nemours & Co., 366 U.S. 316, 334 (1961).

C. Statutory and Regulatory Framework

As set forth in the findings of fact, this case arises from the agreements to settle patent infringement suits brought by Schering, as the manufacturer of the brand name drug K-Dur 20, protected by the '743 patent, against Upsher-Smith and against ESI, as manufacturers of generic drugs, each of which

had filed an Abbreviated New Drug Application ("ANDA") with the FDA that contained a Paragraph IV certification that the '743 patent was invalid or not infringed. In order to fully understand the issues involved herein, an overview of the statutory and regulatory framework from which the challenged agreements arose is necessary.

1. Patent Law

Article 1, Section 8, Clause 8 of the U.S. Constitution empowers Congress "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others - for example, by the initiation of infringement litigation from manufacturing, using and/or selling the invention during the patent term. See 35 U.S.C. § § 101, 154, 271, 281. (The "Patent Act," 35 U.S.C. § § 1 et seq.). The Patent Act also expressly provides that a patent is assignable: the patent owner may "grant and convey an exclusive right under his application for patent ... to the whole or any specified part of the United States." 35 U.S.C. § 261.

The exclusive rights provided for in patent laws are intended to offer an incentive for investors to take risks in performing research and development. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81, 484 (1974); Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229-30 (1964). The Federal Trade Commission recognizes the role of intellectual property laws in promoting innovation and enhancing consumer welfare.

> The intellectual property laws provide incentives for innovation and its dissemination and commercialization

> by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without competitors. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers.

U.S. Dep't of Justice and Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property § 1.0 (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13, 132, at 20,734. The role of patent law in interpreting claims brought under antitrust law is discussed more fully in Section E.4.b. infra.

2. The Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, authorizes the Food and Drug Administration ("FDA") to regulate the marketing and sale of drugs in the United States. 21 U.S.C. §§ 301-397.

An applicant seeking to market a new brand-name drug usually must prepare a New Drug Application ("NDA") for FDA consideration. 21 U.S.C. § 355. Preparing an NDA is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy. F. 13; Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323, 1325 (Fed. Cir. 2001). The NDA must also include a list of patents which claim the drug. 21 U.S.C. § 355(b)(1). If the FDA approves the NDA, it publishes a listing of the drug and patents on the drug's approved aspects in Approved Drug Products with Therapeutic Equivalence

Evaluations, otherwise known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, which simplified the procedure for obtaining approval of generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355. Under the Hatch-Waxman Act, manufacturers of generic drugs are required to submit an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA offers an expedited approval process for generic drug manufacturers. Mylan Pharmaceuticals, 268 F.3d at 1325. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. 21 U.S.C. § 355 (j)(2)(A).

When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patent must certify that the patent on the brand name drug is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. 21 U.S.C. § § 355(j)(2)(A)(vii)(I) to (IV). This is known as a "Paragraph IV Certification." If the ANDA contains a Paragraph IV certification, the ANDA applicant must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. 21 U.S.C. § 355(j)(2)(B)(i). Upon receiving notice of a Paragraph IV certification, the patent holder has 45 days in which to file a patent infringement suit against the generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iii). If a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination

of the patent litigation, or (3) the expiration of a 30-month waiting period. 21 U.S.C. § 355(j)(5)(B)(iii).

The statutory framework of the Hatch-Waxman Act creates the potential for costly patent litigation against the generic maker that files a Paragraph IV-certified ANDA. Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1, 7 (D.D.C. 2001), rev'd on other grounds, 268 F.3d 1323, 1325 (Fed. Cir. 2001). As an incentive to the first generic maker to expose itself to the risk of costly patent litigation, Hatch-Waxman provides that the first to file a Paragraph-IV certified ANDA ("the first filer") is eligible for a 180 day period of exclusivity ("the 180 day Exclusivity Period"). Id.; 21 U.S.C. § 355(j)(5)(B)(iv). That is, during those 180 days, the FDA will not approve any other ANDA for the same generic product until the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patent claiming the brand name drug are invalid or not infringed. Mylan, 139 F. Supp. 2d at 7; 21 U.S.C. § 355(j)(5)(B)(iv).

The provisions of the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds). Thus, although the declared purpose of this legislation was to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962[,]" H.R. Rep. No. 98-857, pt. 1 at 14 (1984), 1984 U.S.C.C.A.N. 2647, Congress expressly recognized the importance of patents.

> Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators

> to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

H.R. Rep. No. 98-857, pt. 1 at 17, 1984 U.S.C.C.A.N. at 2650. Hatch-Waxman does not compel the holder of a valid patent to relinquish the rights it holds pursuant to that patent prior to the expiration date of that patent.

D. Relevant Geographic and Product Market

The determination of the relevant market is essential to all four violations alleged in the Complaint. Violations One and Two of the Complaint allege that the agreements entered into between Schering and Upsher-Smith and between Schering and AHP (ESI) unreasonably restrained commerce. Complaint ¶ 68, 69. Establishing the relevant market is the starting point in a rule of reason case. California Dental Ass'n v. FTC, 224 F.3d 942, 952 (9th Cir. 2000) (proof of relevant geographic and product market necessary for proving injury to competition in rule of reason case); Stratmore v. Goodbody, 866 F.2d 189, 194 (6th Cir. 1989) ("The starting point in a rule of reason case is to identify the relevant product and geographic markets."). See also Twin City Sportservice, Inc. v. Finley & Co., Inc., 676 F.2d 1291, 1300 (9th Cir. 1982) ("It is also worth noting that the effort to find a relevant market in this litigation was not performed without purpose. A definition of a relevant market was necessary in order to assess possible Sherman Act violations."). The plaintiff bears the burden of proof on defining the relevant market. Brokerage Concepts v. U.S. Healthcare, Inc., 140 F.3d 494, 513 (3rd Cir. 1998) ("The burden is on the plaintiff to define both components [geographic and product] of the relevant market."); Double D Spotting Serv. v. Supervalu, Inc., 136 F.3d 554, 560 (8th Cir.

1998). As discussed in Section E.4, infra, rule of reason analysis is required in this case.

Determination of relevant product market is an especially important inquiry here, where Complaint Counsel's proof that the agreements are anticompetitive is based on a finding that Schering had monopoly power. Complaint Counsel's economic expert, Professor Bresnahan, used a three-part test to determine whether the patent settlements between Schering and Upsher-Smith and between Schering and AHP (ESI) were anticompetitive. F. 414. The three-part test asks:

> (1) Does the patent holder have monopoly power?
> (2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
> (3) Is there a payment to the potential entrant to delay its entry? The payment can take any form, as long as it is a net positive value to the entrant.

F. 414. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. F. 415-16. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. F. 414. ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't - wouldn't do anything to harm competition."). By making monopoly power an integral part of that expert's testimony, a determination of relevant market is an integral part of Complaint Counsel's case.

In its post trial briefs, Complaint Counsel suggests that it need not define the relevant product market. Complaint Counsel asserts that direct evidence of anticompetitive effects

"obviates the need, as a matter of law, to undertake the market definition exercise respondents advance." Complaint Counsel's Post Trial Brief ("CCPTB") at 47. Complaint Counsel argues that the Supreme Court "in FTC v. Indiana Fed'n of Dentists ... made clear that proof of actual anticompetitive effects make market definition and market power inquiries unnecessary." CCPTB at 83. However, Indiana Fed'n of Dentists does not relieve Complaint Counsel of its obligation to define the relevant market. Rather, Indiana Fed'n of Dentists holds that proof of actual detrimental effects can obviate the need for an inquiry into market power. FTC v. Indiana Fed'n of Dentists 476 U.S. 447, 460-61 (1986). Complaint Counsel further relies on Toys "R" Us, Inc. v. FTC, which holds that, "in a properly defined relevant market," direct evidence of anticompetitive effects is one way to prove market power. 221 F.3d 928, 937 (7th Cir. 2000). Thus, while Toys R' Us may relieve Complaint Counsel of proving market power, it does not relieve Complaint Counsel from properly defining the market.

Further, Complaint Counsel's suggestion that, because it has presented evidence of anticompetitive effects, it need not present evidence of monopoly power is illogical. Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected.

Moreover, Complaint Counsel's position that it need not prove or define the relevant market clearly undermines the theory and opinions of Complaint Counsel's expert witness, as his test is premised on finding a monopoly and a threat to the monopoly. See CX 1590 (the "three pies" chart); F. 414-16 (if Schering was not a "monopolist" then the Bresnahan Test is not satisfied for anticompetitive agreements).

To prove that the agreements did have anticompetitive effects, Complaint Counsel relied on the testimony of Professor Bresnahan who reached this conclusion based on his finding that Schering was a monopoly and had market power. Without a proper market definition, Bresnahan's opinions are without

proper foundation and lose credibility. The case that was brought involved proof of a relevant product market and the expert premised his analysis on the proof of a monopolist within a relevant product market. Accordingly, Complaint Counsel's proof was not built upon a proper determination of market power or monopoly power.

Violations Three and Four of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and AHP to monopolize the relevant markets. Complaint ¶ 70, 71. Establishing the relevant market is also necessary to assess whether a defendant possesses monopoly power. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455-56 (1993) (to establish monopolization or attempted monopolization it is "necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.") (citations omitted); Walker Process Equip. Inc. v. Food Mach. and Chem. Corp., 382 U.S. 172, 177 (1965) ("Without a definition of that market there is no way to measure [the respondent's] ability to lessen or destroy competition.").

Complaint Counsel bears the burden to establish the relevant market, which is "an indispensable element of any monopolization case." Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1355 (Fed Cir. 1999); see Elliot v. United Ctr., 126 F.3d 1003, 1003-04 (7th Cir. 1997); Alcatel USA, Inc. v. DGI Techs., Inc., 166 F.3d 772, 781 (5th Cir. 1999); H.J., Inc. v. Int'l Tel. & Tel., 867 F.2d 1531, 1537 (8th Cir. 1989) ("The plaintiff carries the burden of describing a well-defined relevant market, both geographically and by product, which the defendants monopolized."). Complaint Counsel did not meet its burden of establishing the relevant product market.

1. Geographic Market

The relevant geographic market is the region "in which the seller operates, and to which the purchaser can practicably turn for supplies." Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327 (1961). Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose products have been approved for sale in the United States by the FDA. F. 26. Schering and Upsher-Smith have FDA approval and do sell their potassium chloride supplements in the United States. F. 25-28. Therefore, the relevant geographic market for assessing the allegations of the Complaint is the United States. F. 25-28

2. Product Market

The Complaint alleges:

> The relevant markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

Complaint ¶ 21. At trial, Complaint Counsel's position was that the relevant product market is 20 milliequivalent potassium chloride tablets and capsules. F. 30.

Respondents argue that the evidence does not support Complaint Counsel's alleged product market of 20 mEq sustained release potassium chloride tablets.

The greater weight of credible evidence shows that the relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. F. 29-118.

a. Functional interchangeability of potassium supplements

The relevant market for purposes of antitrust litigation is the "area of effective competition" within which the defendant operates. Tampa Elec., 365 U.S. at 327-28. As the Supreme Court explained in E.I. du Pont Nemours:

> The 'market' which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The tests are constant. The market is composed of products that have reasonable interchangeability for the purposes for which they are produced -- price, use and qualities considered.

351 U.S. at 404.

In defining a relevant product market, courts look to determine if products are "reasonably interchangeable." Courts consistently look to reasonable interchangeability as the primary indicator of a product market. See United States v. Continental Can Co., 378 U.S. 441, 453-57 (1964) (glass jars and metal cans sufficiently interchangeable to be in the same market); Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715, 722, 726 (3d Cir. 1991) (relevant product market consisted of "Ford and other comparable tractors" based on reasonable interchangeability); Kaiser Aluminum & Chem. Corp. v. F.T.C., 652 F.2d 1324, 1330 (7th Cir. 1981) ("the clearest indication that products should be included in the same market is if they are actually used by consumers in a readily interchangeable manner"); F.T.C. v. R.R. Donnelley & Sons Co., 1990-2 Trade Cas. (CHH) ¶ 69,239 at 64,854-55 (D.D.C. 1990) (offset and gravure print processes interchangeable and in the same product market); In re Liggett & Myers, Inc., 87 F.T.C. 1074, 1163 (1976) (premium and economy dog food found to be in

the same market in view of interchangeability of use). See also In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) ("The pharmaceutical market is fundamentally different from the market for other products. In the pharmaceutical industry, there is a government-assured complete interchangeability of drug products.").

The first step in determining interchangeability of potassium supplements is to determine who makes the selection regarding which potassium supplement to be used. Potassium supplements are given by doctors to hypertensive patients to treat or prevent hypokalemia, a lack of potassium caused by the use of diurelic medications. F. 38. The doctor is the most important link in the chain of those involved in the decision of which potassium supplement to prescribe. F. 38, 118. The doctor diagnoses that a potassium supplement is required for the patient. F. 38, 118. The doctor is the one who is knowledgeable about what products/drugs are available to meet the patient's needs. Professor Bresnahan acknowledged that the demand for potassium begins with a patient presenting himself/herself to a doctor and receiving a potassium supplement prescription. F. 38, 118.

There is insufficient evidence to show that the patient has any control over this decision. After the doctor makes the diagnosis and writes the prescription, the pharmacy fills that prescription. F. 39, 118. The patient and/or medical insurance pay for the prescription. The credible evidence demonstrates that the pharmacist has little or no control over which potassium supplement product to dispense. In many states, the law allows no change. In some states, a generic may be substituted. F. 22-23. Thus, between the doctor, the pharmacist, and the patient, it is the doctor who exercises most, if not all, control over which potassium supplement product is selected for any given patient. Accordingly, the only logical place from which to determine the relevant product market is

from the array of therapeutically substitutable choices available to the doctor.

In 1997, more than 25 firms sold potassium supplements, including Schering-Plough and Upsher-Smith. F. 31-37. All forms of potassium are considered to be therapeutically equivalent; they all deliver potassium. F. 43-48. The high degree of interchangeability between various potassium products, including 20 mEq sustained-release products, was confirmed by Complaint Counsel's fact witnesses, Dean Goldberg and Russell Teagarden. F. 49-55.

Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. F. 50. Goldberg further testified that most, if not all, potassium chloride products are therapeutically equivalent. F. 50. Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. F. 50.

Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM"), testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. F. 51-54. If Merck-Medco and other PBMs thought that unique characteristics existed that warrant a separate market for just 20 mEq sustained release potassium chloride products, there would be a separate classification on Merck-Medco's formulary. F. 51-54. He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medco did not even list K-Dur 20 as a prescription drug on its formulary. F. 51-54. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmaceutical companies. F. 51.

In addition, Professor Bresnahan conceded that K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-Lyte, Klotrix, Apothecon KCl and Ethex potassium chloride were all

prescribed for the same "purpose" of treating potassium deficiency. F. 87.

The evidence demonstrates that many types of potassium supplements are interchangeable with K-Dur 20. Accordingly, because there are many other acceptable potassium supplements which may be substituted, the relevant market is not limited to 20 mEq potassium supplements.

b. Pricing of potassium supplements

Complaint Counsel has taken the position that the proper inquiry to determine the relevant market is not whether the products are functionally interchangeable, but whether the products constrained each other's prices. CCPTB at 85-86. Complaint Counsel relies on In re Coca-Cola Bottling Co. of the Southwest, which held that the relevant inquiry in conducting an antitrust analysis is not whether "certain [products] competed against each other in a broad sense," but instead whether such "products were sufficiently substitutable that they could constrain" each other's pricing. 118 F.T.C. 452, 541-42 (1994). Coca-Cola Bottling was a merger case with an overriding focus on the combined power to influence the market which would be wielded by the proposed merger partners. In addition, as stated below, Coca-Cola Bottling cited Brown Shoe with approval. Id.

The Commission has not limited the inquiry to whether certain products are sufficiently substitutable that they could constrain each others products. E.g., Int'l Assoc. of Conference Interpreters, 123 F.T.C. 465, 640 (1997) (Section 2 case) (the Commission generally examines what products are reasonable substitutes for one another through a consideration of price, use and qualities). Moreover, in the context of prescription of drugs, the Commission in, In re Warner Lambert Co., 87 F.T.C. 812, 877 (1976), found that branded and unbranded thyroid

products constituted a single product market despite "lack of price elasticity."

Complaint Counsel cites to numerous cases for the assertion that a price difference can lead to a finding of a separate product market. CCPTB at 85 and 86 n.33. But these cases utilize the Supreme Court's Brown Shoe analysis and virtually always consider other Brown Shoe factors such as special characteristics, industry recognition, distinct customers, and other Brown Shoe "practical indicia." See FTC v. Staples, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997) (extensive reliance on Brown Shoe "practical indicia" for product market, including special characteristics of office superstores, industry recognition, extensive evidence of cross-elasticity of demand); FTC v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 45 (D.D.C. 1998) (relies on Brown Shoe, in particular unique features of the drug wholesaling industry, including specialized customers such as hospitals dependent on wholesalers, to find a distinct product market; merger case); Coca-Cola, 118 F.T.C. at 541-42 (citing Brown Shoe with approval and conducting extensive review of sales channel differences between home market and cold drink market); In re Olin Corp., 113 F.T.C. 400, 603 (1990) (liquid chlorine pool bleach in separate market from dry pool sanitizer where "physical and technical characteristics" differed; chemical concentration of active ingredient, chlorine, differed; shelf life differed; and customers were geographically distinct and functionally distinct pool service companies vs. homeowners).

The pharmaceutical industry case Complaint Counsel cites, Smith-Kline Corp. v. Eli Lilly & Co., 575 F.2d 1056 (3d Cir. 1978), found cephalosporin antibiotics to be a distinct product market from other antibiotics not because of price difference, but because, applying Brown Shoe, the Third Circuit found cephalosporins had special characteristics. Cephalosporins were (a) broad spectrum antibiotics "effective against a wider range of infectious organisms than are other antibiotics;" id. at

1064; ("cephalosporins are effective against the organism Klebsiella" staphylococci and gram negative bacilli, as contrasted with penicillins that "tend to be active against one but not the other"); (b) used for specialized patients: "cephalosporins are generally used in treating penicillin-allergic patients," id. at 1064; and (c) were "less toxic" than some other anti-infectives. Id. These "sufficiently unique features" are not present here where K-Dur 20 and other potassium chloride products contain precisely the same therapeutic agent and are "therapeutically equivalent."

c. Complaint Counsel did not prove a single brand market

Although Complaint Counsel claims it does not have to prove relevant market, Complaint Counsel alleges that Schering had market power and a monopoly in the market for 20 mEq potassium supplement. However, at all times relevant, Schering had a valid patent for the 20 mEq potassium supplement. Therefore any monopolization or market power existed by virtue of the '743 patent. See Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 16 (1984) (When the government has granted the seller "a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.")

d. Complaint Counsel did not present pricing data to support an Indiana Federation of Dentists analysis

Complaint Counsel cites to Indiana Fed'n of Dentists, 476 U.S. at 460-61, to show that "proof of actual detrimental effects ... can obviate" the need for an inquiry into market power. CCPTB at 83. However, as discussed infra, the pricing evidence offered by Complaint Counsel's expert is inadequate

in many respects and does not support an Indiana Federation analysis.

Complaint Counsel's expert Professor Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for Klor Con 10 or Klor Con 8 potassium products and did not have or offer pricing data on other competitors. F. 419. Complaint Counsel's expert did not study the costs of Schering or other potassium supplement producers. F. 423. Complaint Counsel's expert did not study rebates, promotional allowances, or free goods, that affect the net pricing that Schering's customers received. F. 424.

Although Complaint Counsel sought to demonstrate that the price of K-Dur 20 rose, proof of one firm's prices rising, in a vacuum, cannot lead to any inference as to the relative price increase or decrease of Schering's K-Dur 20 product over time. An analysis under Indiana Federation requires that more be proven. See Levine v. Central Florida Med. Affiliates, 72 F.3d 1538, 1552 (11th Cir. 1996) (plaintiff's proof that defendant's prices (doctor's fees) had risen was legally insufficient because there was no proof of other doctors' fees or costs to compare those price increases with). Also, potassium purchasers had more than 20 firms to choose from to obtain therapeutically equivalent product, F. 31-37, clearly sufficient alternative choices to defeat an Indiana Federation claim. See Flegel v. Christian Hosp., N.E.-N.W., 4 F.3d 682, 689 (8th Cir. 1993) (plaintiff provided insufficient evidence of detrimental effects under Indiana Federation where patients had the option of receiving care at other hospitals).

e. Complaint Counsel did not present a legally cognizable submarket under Brown Shoe

Brown Shoe v. United States, 370 U.S. 294, 325 (1962) introduced into merger law the concept of submarkets within the relevant market. Rothery Storage & Van Co. v. Atlas Van

Lines, Inc., 792 F.2d 210, 218 (D.C. Cir. 1986). The Supreme Court identified several "practical indicia" that may be used to delineate submarkets:

> The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

Brown Shoe, 370 U.S. at 325. "These indicia seem to be evidentiary proxies for direct proof of substitutability." Rothery Storage, 792 F.2d at 218; H.L. Inc., 867 F.2d at 1540 ("[T]he same proof which establishes the existence of a relevant product market also shows (or in this case, fails to show) the existing of a product submarket.").

Complaint Counsel argues that a Brown Shoe analysis is not appropriate. Nevertheless, the Complaint specifically defined 20 milliequivalent extended-release potassium chloride tablets and capsules as a "narrower market" contained within the relevant market of all potassium chloride supplements approved by the FDA. Complaint at ¶ 21. Thus to determine whether "20 milliequivalent extended-release potassium chloride tablets and capsules" is a separate submarket, a Brown Shoe analysis follows.

1. "Industry Or Public Recognition" Of Distinct Markets

Complaint Counsel did not prove that the industry recognizes the existence of distinct markets between potassium chloride products and 20 mEq sustained-release potassium chloride tablets and capsules. Complaint Counsel's fact

witnesses from Merck-Medco and United HealthCare, two important industry participants, provided no testimony to prove that the industry recognizes 20 mEq sustained-release potassium chloride products as a separate and distinct market from the overall potassium chloride market. F. 49-55.

In applying this factor, courts look to industry publications, the classification of a class of products in a separate class, perceptions of customers and the firms' marketing documents. See, e.g., Moore Corp. v. Wallace Computer Servs., Inc., 907 F. Supp. 1545, 1576 (D. Del. 1995) (citation omitted). These materials uniformly support a broad potassium supplement market; Professor Bresnahan admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product with unique features. F. 81. Data from IMS has a single category, 60110, for "Potassium Supplement Chloride" in which K-Dur 20 is but one of more than 30 products sold by more than 25 different firms tracked by IMS. F. 83.

Professor Bresnahan conceded that Schering's marketing documents for K-Dur 20 use the entire potassium chloride supplement market as a measure of performance and also consider other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. F. 60. Schering tracked the progress of its substantial investment in advertising and marketing by monitoring market share gains in terms of the overall potassium market. F. 60. Even Bresnahan and Complaint Counsel relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. F. 60. The marketing documents of Schering's potassium rival, Upsher-Smith, demonstrate that one of the major competitors to the Upsher-Smith Klor Con product line, including the Klor Con 10 wax matrix, was K-Dur 20. F. 60 Upsher-Smith targeted K-Dur 20 in a series of advertisements urging doctors to substitute two Klor Con 10s for a 20. F. 64-69. Thus, the marketing perceptions of both companies were that K-Dur 20 competed in the broader potassium market. See,

e.g., Moore, 907 F. Supp. at 1576 ("neither company has historically considered [the product at issue] as a category unto itself;" finding broader product market under Brown Shoe).

2. "Product's Peculiar Characteristics And Uses"

As detailed in the preceding section, Complaint Counsel did not prove that K-Dur 20 has "peculiar characteristics and uses" than other potassium supplements. All potassium supplements have the same purpose: to deliver potassium to hypokalemic patients. F. 43-48.

3. "Unique Production Facilities"

Complaint Counsel presented no evidence that K-Dur 20 and its generic equivalents are manufactured in different plants or require different production facilities. In fact, Professor Bresnahan conceded at trial that the 10 and 20 mEq products are produced in the same plant. F. 85-86. With the same production facilities, the product facility factor cannot support a separate K-Dur 20 product market. See, e.g., United States v. Consol. Foods Corp., 455 F. Supp. 108, 125 (E.D. Pa. 1978) (fresh and frozen institutional pies in same product market under Brown Shoe where "[m]anufacturing facilities for both products are virtually the same").

4. "Distinct Customers"

Complaint Counsel did not prove that K-Dur 20 is directed toward a distinct class of customers. In fact, Bresnahan testified that there is no distinct class of customers that prefer K-Dur 20, F. 87-88 (Bresnahan unaware of any group of potassium deficient patients that cannot by treated by Klor Con 10; Bresnahan "has seen nothing in those terms."). Similarly,

Phillip Dritsas testified that there is no unique subgroup of patients that can only take K-Dur 20. F. 87-88.

5. "Distinct Prices"

Under this factor, for product lines to be considered separate, each potentially definable market must have distinct prices. See U.S. Healthcare, Inc. v. Healthsources, Inc., 986 F.2d 589, 598-99 (1st Cir. 1993). Complaint Counsel failed to introduce sufficient evidence or testimony of distinct prices in the 20 mEq sustained-release potassium chloride tablet and capsule market, as compared with other potassium products. Instead, Complaint Counsel's witness, Mr. Teagarden, conceded that K-Dur has the same relative price as other potassium chloride supplements. F. 89. Bresnahan conceded that branded potassium products had "comparable" prices to K-Dur 20. F. 89.

The only specific pricing difference that appeared in Bresnahan's Report was a 30% pricing difference between only a small group of the potassium unbranded generic products, and this difference actually proved the cross-elasticity of demand between unbranded generics and K-Dur 20 in 1996. Bresnahan presented no statistical pricing study, and did not even have a pricing data set for K-Dur 20, a price data set for K-Dur 10 or for Klor Con 10, and for its competitors in the sale of potassium supplements. F. 91, 419, 428.

Bresnahan concedes that a pricing difference alone does not suffice to prove a separate product market. F. 91 Nor did he study the demand for various forms of potassium to calculate demand elasticities. F. 422. Professor Bresnahan did not study the ratio of Schering's prices to costs, so he is unable to evaluate any rise in Schering's price for K-Dur 20 as related or unrelated to costs. F. 423.

6. "Sensitivity To Price Changes"

Complaint Counsel did not introduce sufficient evidence to demonstrate that there is price sensitivity between other potassium chloride supplements and K-Dur 20. Complaint Counsel's sole expert economist failed to conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. F. 112, 113, 419-23. Bresnahan had no pricing data sets for Schering, Upsher-Smith, Apothecon, or any other potassium competitor. F. 419. Lack of this evidence undermines Complaint Counsel's claims. See, e.g., Lantec, Inc. v. Novell, Inc., 146 F. Supp. 2d 1140, 1148-49 (D. Utah 2001) (granting defendants' motion for judgment as a matter of law against Section 1 and 2 claims "[b]ecause there is no evidence on the costs of the various products or of how the consumer would react to a price increase in such costs, there is no evidence of price sensitivity" under Brown Shoe and thus plaintiffs' "evidence is insufficient to establish their definition of the relevant market").

The record evidence actually shows not only price sensitivity in the market, but also K-Dur 20 losing some market share to other potassium chloride products. The record evidence showed that the 30% price difference between K-Dur 20 and the unbranded generic potassium products was causing the sales of the generic products to rise, as set forth in the K-DUR Marketing Plan (CX 20), written just six weeks after the June 1997 Agreement became effective:

> Klor Con 10, a branded generic, has grown to 16% of total prescriptions. The category of generics has grown over a full point to 30% of total prescriptions. The growth in the generic market is due in part to the 30% price advantage over K-DUR 20, but managed care also plays a significant role.

F. 110; CX 20 (1998 K-Dur Marketing Plan, August 1, 1997, at SP 4040).

Similarly, the price sensitivity of the market to price reductions was dramatically demonstrated by the shift in sales to Apothecon, a new entrant in the sale of potassium supplements. F. 104-08. Price discounting was repeatedly noted in Upsher-Smith's potassium marketing documents. F. 104-08.

Furthermore, Bresnahan did not evaluate the brand advertising conducted by Schering. F. 424. Schering-Plough put millions of dollars into promoting the K-Dur brand and K-Dur 20 during the 1995-1997 time period. F. 411. Schering also invested heavily in free goods, rebates and other forms of discounting and marketing. 114-16. The magnitude of these expenditures demonstrates the price sensitivity of potassium supplement purchasers and the fact that Schering viewed itself as facing competition from various forms of potassium supplements prior to September 1, 2001. From October 1, 1997 to June 30, 2001, Schering spent $136 million in rebates it paid K-Dur customers. F. 115.

Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and physician awareness activities. F. 411. This extensive advertising campaign was designed to compete against generic forms of potassium supplements. F. 411.

7. "Specialized Vendors"

The last Brown Shoe factor asks whether there are "specialized vendors" unique to K-Dur 20. No specialized vendors serve only 20 milliequivalent extended-release potassium chloride tablets and capsules. Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. F. 118. Prescriptions for extended-

release potassium chloride supplements are dispensed at pharmacies. F. 118.

Complaint Counsel's witnesses did not establish by sufficient evidence any of these factors in order to prove that K-Dur 20 and its generic equivalents are a separate product market. Thus, an application of these "practical indicia" to the evidence presented at trial reveals that "K-Dur 20 and its generic equivalents" is not a separate product market.

E. First and Second Violations of the Complaint

The Complaint charges Respondents with four violations. The First and Second Violations of the Complaint charge that the agreements between Schering and its horizontal competitors, Upsher-Smith and AHP, unreasonably restrained commerce and therefore each agreement was an unfair method of competition.

1. The Legal Framework for Analysis of Horizontal Restraints

The FTC Act's prohibition of "unfair methods of competition" encompasses violations of other antitrust laws, including Section 1 of the Sherman Act, which prohibits agreements in restraint of trade. California Dental Ass'n, 526 U.S. at 763 n.3. The Commission relies on Sherman Act law in adjudicating cases alleging unfair competition. E.g., Indiana Fed'n Dentists, 476 U.S. at 451-52 (Commission based its ruling that the challenged policy amounted to a conspiracy in restraint of trade that was unreasonable and hence unlawful under the standards for judging such restraint developed in the Supreme Court's precedents interpreting § 1 of the Sherman Act); In re California Dental Assn., 121 F.T.C. 190, 292 n.5 (1996); In re American Med. Assoc., 94 F.T.C. 701, 994 (1979).

Restraints on trade have been held unlawful under Section 1 of the Sherman Act, either when they fall within the class of restraints that have been held to be unreasonable per se, or when they are found to be unreasonable after a case-specific application of the rule of reason. In some circumstances, an abbreviated, or "quick look" rule of reason analysis may be appropriate. California Dental, 526 U.S. at 770. Complaint Counsel asserts that the challenged agreements are unreasonable restraints of trade under either the per se or rule of reason analysis. Although Complaint Counsel does not specifically urge "quick look" treatment, because many of the arguments Complaint Counsel advances relate to an abbreviated rule of reason approach, this method of analyzing the agreements is also addressed. Regardless of the method of analysis employed, the essential inquiry remains the same -- whether or not the challenged restraint enhances or impairs competition. National Collegiate Athletic Assn. v. Bd. of Regents, 468 U.S. 85, 104 (1984) ("NCAA").

2. The Per Se Approach Is Not Applicable

"[M]ost antitrust claims are analyzed under a 'rule of reason' ...." State Oil Co. v. Kuhn, 522 U.S. 3, 10 (1997)(citations omitted); Standard Oil, 221 U.S. 1, 62 (1911); Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918)(courts generally determine the reasonableness of a particular agreement by reference to the surrounding facts and circumstances under the rule of reason). Courts are free to depart from this analysis, and adopt per se rules, only in limited circumstances, after they have had sufficient experience with a particular type of restraint to know that it is manifestly anticompetitive. Broadcast Music, Inc. v. Columbia Broad Sys., Inc., 441 U.S. 1, 9 (1979); Continental T.V. Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 (1977)(the per se rule should only apply to conduct that has a "pernicious effect on

competition" and "lack[s] ... any redeeming virtue"). Examples of such practices are horizontal price fixing, United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940), FTC v. Sup. Ct. Trial Lawyers Ass'n, 493 U.S. 411 (1990); agreements to reduce output, NCAA, 468 U.S. at 99; territorial divisions among competitors, United States v. Topco Assoc., Inc., 405 U.S. 596, 608 (1972); and certain group boycotts. Northwest Wholesale Stationers v. Pac. Stationery & Printing Co., 472 U.S. 284, 289-90 (1985). "[C]ertain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused." Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984). See also Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990); Topco Assoc., Inc., 405 U.S. 596, 608 (1972).

To fit its allegations into the per se category, Complaint Counsel advances two theories. First, Complaint Counsel characterizes the agreements as "temporal market allocations," dividing the time remaining on Schering's patent. Second, Complaint Counsel asserts that the agreements reduced output and increased prices by keeping Upsher-Smith's and AHP's cheaper generic versions of K-Dur 20 off the market until September 2001 and January 2004, respectively. However, the settlement agreements fit neither of these molds. Further, because an agreement to settle patent litigation must be examined in the context in which the agreement arose, the per se approach is not appropriate.

a. Complaint Counsel has not presented a per se market division case

Complaint Counsel asserts, "[e]ach agreement is in economic substance a temporal market allocation arrangement, in which sales of K-Dur 20 are reserved to Schering for several years, while Upsher-Smith and AHP are required to refrain

from selling their generic versions of K-Dur 20 during that time period. As such, each constitutes a horizontal market allocation agreement, a classic per se violation." CCPTB at 65. However, this case does not present a straight forward market division case. Rather, the claims, as framed by Complaint Counsel, raise two novel issues. First, whether a patent holder and a challenger to that patent can settle patent litigation with an agreement that divides the time remaining on the patent. Second, whether a patent holder can make a "reverse payment" to settle a patent dispute.

The classic per se violation cases involve territorial or geographic divisions of markets. Palmer, 498 U.S. at 49-50 (competitors agreed not to enter each other's territories and to share profits from sales in one of those territories); Topco Assoc., 405 U.S. at 607-08 ("One of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"). With the exception of the Cardizem and Terazosin cases, Complaint Counsel has cited no case that holds that a "temporal market allocation" is a per se violation and no case that prohibits a patent holder from allocating the time remaining under its patent by retaining the exclusive rights guaranteed by the patent for a number of years and then granting licences under the patent to allow manufacturers of generic versions to compete for the remaining time. See In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682 (E.D. Mich. 2000); In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340 (S.D. Fla. 2000). See also Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001).

The Cardizem and Terazosin cases can be distinguished on numerous grounds. The critical difference, though, is that those agreements did not involve final settlements of patent litigation; and they did not involve agreements permitting the generic company to market its product before patent expiration. In

Terazosin, the court found: "Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage." 164 F. Supp. 2d at 1350. Likewise, in Cardizem, the challenged agreement "did not resolve the pending patent claims; ... Rather than facilitating or fostering an expeditious resolution of the HMRI/Andrx patent infringement suit, ... [the agreement and payments] created the incentive to pursue the litigation beyond the district court and through the appellate courts." 105 F. Supp. 2d at 705.

In addition, Complaint Counsel's challenge to what Complaint Counsel has characterized as "reverse payments" is far from an "established" antitrust violation. The novelty of challenges to "reverse payment" patent infringement settlements was acknowledged by Complaint Counsel's expert witnesses at trial. Professor Bresnahan testified that there was no economic literature on the topic of reverse payments prior to the filing of suit in this case. Bresnahan, Tr. 644-45. Professor Bazerman testified that he had never heard of the phrase "reverse payments" prior to his work in this case. Bazerman, Tr. 8569. Applying a per se rule to a practice that is so new would be inappropriate. Broadcast Music, Inc., 441 U.S. at 9; Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 344 (1982).

Courts have been reluctant to create new per se rules. Indiana Fed'n of Dentists, 476 U.S. 447, 458-59 (1986) ("We have been slow ... to extend per se analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious."); Broadcast Music, Inc., 441 U.S. at 9 ("[I]t is only after considerable experience with certain business relationships that courts classify them as per se violations.") See also Maricopa County, 457 U.S. 332, 344 (1982) ("Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn

it, it has applied a conclusive presumption that the restraint is unreasonable.").

The few decisions by U.S. district courts adjudicating claims arising from the agreements entered into between Hoechst Marion Roussell and Andrx and between Abbott and Zenith and Geneva hardly constitute "considerable" experience. Further, the factual differences between the challenged agreements in Cardizem and Terazosin and the challenged agreements here distinguish those cases from the instant one. Without established case law holding that temporal market allocations pursuant to a patent or payments in connection with the settlement of patent litigation are per se violations, the "considerable experience" needed to support per se condemnation is lacking and application of the per se rule is inappropriate.

b. Complaint Counsel has not presented a per se case of reduced output and increased prices

Complaint Counsel alleges "that the challenged payments to stay off the market directly limit competition on price and output and are inherently likely to delay the entry of lower-priced alternatives and to enable Schering to maintain high prices without fear of losing market share." CCPTB at 65. This case, however, does not present a straightforward case of an agreement to reduce output or set prices.

The agreements, on their face, set no limits on output or prices and Complaint Counsel does not argue that Schering dictated the price at which Upsher-Smith and ESI may sell their products or the quantities they may sell upon entry. The agreements do, however, establish that Upsher-Smith and ESI may not enter the market with their generic versions of K-Dur 20 until September 2001 and January 2004, respectively. Complaint Counsel makes the argument that, by setting these

entry dates, Respondents, in effect, limited the output - by eliminating Upsher-Smith's and ESI's output - that would have been available for the periods of up until September 2001 and January 2004. Complaint Counsel further argues that, because Schering was unrestrained from competition from the generics, the agreements enabled Schering to increase prices by charging supra competitive prices for K-Dur 20.

Complaint Counsel's argument ignores the critical fact that these agreements are agreements to settle patent litigation. There is no evidence that the '743 patent is invalid. F. 124. There is no evidence that Schering's initiation of the patent infringement suits against Upsher-Smith and ESI was not for purposes of defending the '743 patent. F. 128, 331. Indeed, Hatch-Waxman encourages patent holders to initiate patent litigation to defend their patents by requiring ANDA applicants to notify patent holders of Paragraph IV Certifications and imposing a 45 day framework for patent holders to initiate patent infringement suits against generic manufacturers. 21 U.S.C. § 355(j); Mylan, 139 F. Supp. 2d at 9. Unless determined to be invalid, the '743 patent gives Schering the right to limit output - by excluding manufacturers of infringing drugs from the market until September 2006. See 35 U.S.C. §§ 101, 271, 281. Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 135 (1969) ("The heart of his legal monopoly is the right to ... prevent others from utilizing his discovery without his consent."). And, this patent gives Schering the right to charge monopolistic prices for its patented product. "Such an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." United States v. Studiengesellschaft Kohle, M.B.H., 670 F.2d 1122, 1128 (D.C. Cir. 1981).

It is not immediately obvious whether output was reduced and prices were increased by operation of Schering's legal, patented monopoly or by operation of the agreements entered

into between Schering and Upsher-Smith and Schering and ESI. Further, because it is not immediately obvious that Upsher-Smith or ESI could have entered the market sooner than the agreed upon dates, it is not immediately obvious that output was reduced. "[T]he Supreme Court has made it clear that the per se rule is a 'demanding' standard that should be applied only in clear cut cases." Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998) (citing Continental T.V., 433 U.S. at 50). Because this case does not present a clear cut case of restraints where the economic impact is "immediately obvious" (Indiana Fed'n of Dentists, 476 U.S. at 459), per se treatment is not appropriate and a full rule of reason analysis is required.

c. The agreements challenged by Complaint Counsel are not in the class of agreements with no redeeming virtues

Settlements of intellectual property lawsuits are not in a class of per se agreements that, in the words of the Supreme Court in White Motor Co. v. United States, 372 U.S. 253 (1963) "lack ... any redeeming virtue." Id. at 263. All settlements have redeeming virtue, providing important procompetitive benefits that must be taken into consideration in any antitrust analysis. See, e.g., Speed Shore Corp. v. Denda, 605 F.2d 469, 473 (9th Cir. 1979) (c[illegible] must balance "deeply-instilled policy of settlement[s]" against claim that patent settlement unreasonably restrain[s] trade); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) ("Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming .... By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes who support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute."). For example, one of Schering's

expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. F. 384. Mr. Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. F. 384. This is especially true of settlements of patent infringement cases, like the Upsher-Smith and ESI settlements. See Grunin v. Int'l House of Pancakes, 53 F.2d 114, 123 (8th Cir.), cert. denied, 423 U.S. 864 (1975) ("The very purpose of compromise is to avoid the delay and expense of such a trial."); Boston Scientific Corp. v. Schneider (Europe) AG, 983 F. Supp. 245, 270-71 (D. Mass. 1997) (upheld settlement agreement as not anticompetitive based on the "general rule that settlements and cross-licensing agreements do not, without something more, violate the antitrust laws."). Under the Upsher-Smith settlement agreement, for example, consumers are enjoying low priced generic versions of K-Dur 20 today. In the absence of the settlement, it is impossible for anyone to say whether there would be generic competition today or not because we can't know who would have won the litigation. See Bresnahan, Tr. 8230.

Although the Supreme Court has utilized the per se approach in cases involving settlements of patent disputes, in each of those cases, the patent holder engaged in conduct that reached beyond the rights conferred by the patent and engaged in conduct that was in violation of antitrust law. E.g., United States v. Masonite Corp., 316 U.S. 265, 282-83 (1942) (finding licensing agreement where patent holder set prices a violation of Sherman Act); United States v. Singer Mfr. Co., 374 U.S. 174, 197 (1963) (finding patent interference settlement unlawful where the dominant purpose of a settlement was not to settle priority, but to exclude a mutual competitor of the parties); U.S. v. New Wrinkle Inc., 342 U.S. 371, 380 (1952)

(finding a licensing agreement between patent owner and manufacturer which served as means for owner to set prices a per se violation of Sherman Act); U.S. v. Line Material Co., 333 U.S. 287, 314-15 (1948) (finding agreements to cross license patents which fixed the price of the patented device a per se violation). As analyzed below, the conduct engaged in by Schering was not proven to be beyond the rights conferred by the patent. Accordingly, these cases do not command the application of the per se rule.

d. The effects of the agreements cannot be presumed

Complaint Counsel argues that the anticompetitive effects of these agreements are so clear that the restraints should be deemed per se unreasonable. CCPTB at 46, 65. Northern Pacific Ry. v. United States, 356 U.S. 1, 5 (1958) ("[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable."). It is inappropriate in this case, however, to presume effects, for to do so would require a presumption that the '743 patent was either invalid or not infringed by Upsher-Smith's and ESI's products. As discussed in Section E.4.b. infra., to make this presumption would be contrary to law and the substantial, reliable evidence presented at trial. Accordingly, effects will not be presumed and the agreements will be analyzed under the rule of reason approach.

3. The Quick Look Approach Is Not Applicable

An abbreviated or "quick look" analysis under the rule of reason may be utilized when "the great likelihood of anticompetitive effects can easily be ascertained." California Dental Ass'n, 526 U.S. at 770. Quick look analysis may be

appropriate to analyze agreements to restrict output. NCAA, 468 U.S. at 110 ("naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis"). However, where the "anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints" than can be performed using an abbreviated rule of reason analysis. California Dental Ass'n, 526 U.S. at 759.

The case presented by Complaint Counsel fails to present a situation in which the likelihood of anticompetitive effects is obvious. It is possible that Upsher-Smith and ESI might have entered the market prior to September 2001 and January 2004, respectively. However, it is also of course possible that they might not have entered the market until September 2006, upon the expiration of Schering's patent, or not at all. Faced with a set of different conflicting possibilities, the Supreme Court in California Dental Ass'n, held "that the plausibility of competing claims about the effects of the professional advertising restrictions rules out the indulgently abbreviated review to which the Commission's order was treated. The obvious anticompetitive effect that triggers abbreviated analysis has not been shown." 526 U.S. at 778.

Here, Complaint Counsel has presented one plausible explanation for Schering's payments of $60 million to Upsher-Smith and of $15 million to ESI - that these were payments to delay the generics' entry in the market. But, as analyzed infra, this explanation is based largely on the opinion testimony of Complaint Counsel's economic expert that manufacturers of brand name drugs have economic incentives to keep generic manufacturers off the market in order to retain monopoly profits. This explanation is also based on the opinion testimony of Complaint Counsel's valuation expert who testified that Schering's payment to Upsher-Smith was grossly excessive. Respondents also offer plausible explanations, supported by

evidence, - that the payments were made to settle legitimate patent disputes and for separate pharmaceutical products at fair value. Given the plausibility of competing claims about whether the payments were only for delay, the obvious anticompetitive effect "that triggers abbreviated analysis has not been shown" (California Dental Ass'n, 526 U.S. at 778) in this case.

4. Under the Rule of Reason, Complaint Counsel Has Not Demonstrated That These Agreements Are Illegal

a. Complaint Counsel must prove effect on competition

In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition. "The Supreme Court has made clear that the rule of reason contemplates a flexible enquiry, examining a challenged restraint in the detail necessary to understand its competitive effect." In re California Dental Assoc., 121 F.T.C. at 308 (citing NCAA, 468 U.S. at 103-110) "An analysis of the reasonableness of particular restraints includes consideration of the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption." Topco Assoc., 405 U.S. at 607. See also Todd v. Exxon Corp., 275 F.3d 191, 214 (2d Cir. 2001) (plaintiff must present evidence to support allegation that challenged conduct had anticompetitive effect); All Care Nursing Service, Inc. v. High Tech Staffing Servs., Inc., 135 F.3d 740, 749 (11th Cir. 1998) ("To satisfy the rule of reason, the plaintiff must prove that the [conduct] had an adverse effect on competition.").

The fact that a case proceeds under Section 5 of the FTC Act does not alter the requirement that anti-competitive effects

must be proved with evidence. See California Dental Assoc. v. FTC, 224 F.3d 942, 958-59 (9th Cir. 2000) (FTC's failure to demonstrate substantial evidence of a net anticompetitive effect resulted in remand with direction that the FTC dismiss its case). See also Boise Cascade Corp. v. FTC, 637 F.2d 573, 582 (9th Cir. 1980) (absence of evidence reflecting an anticompetitive effect rendered Commission order unenforceable); see also E.I. duPont de Nemours & Co. v. FTC, 729 F.2d 128, 141 (2d Cir. 1984) (challenged practice can only be found to be unfair method of competition under § 5 if weight of evidence shows competition substantially lessened and clear nexus between challenged conduct and adverse effects); see also Interpreters, 123 F.T.C. at 640 (Complaint Counsel failed to demonstrate anticompetitive effects of certain association rules).

The cases relied upon by Complaint Counsel, Summit Health, Ltd. v. Pinhas, 500 U.S. 322, 330 (1991) and Goldfarb v. Virginia State Bar, 421 U.S. 773, 785 (1975), do not support Complaint Counsel's proposition that Complaint Counsel need not prove or quantify actual effects to support a claim under Section 5. Summit Health holds that a defendant need not prove an actual effect on interstate commerce in order to establish federal jurisdiction. 500 U.S. at 330 ("'If establishing jurisdiction required a showing that the unlawful conduct itself had an effect on interstate commerce, jurisdiction would be defeated by a demonstration that the alleged restraint failed to have its intended anticompetitive effect. This is not the rule of our cases.'") (citation omitted). Goldfarb holds that in order to establish that a challenged activity affects interstate commerce, plaintiff need not quantify the expected effect. 421 U.S. at 785. "[O]nce an effect is shown, no specific magnitude need be proved." Id. Thus, Complaint Counsel is not relieved of showing effects simply because this case was brought under Section 5 of the FTC Act, and not under Section 1 of the Sherman Act.

b. Complaint Counsel has not proven that the agreements delayed competition

Complaint Counsel alleges that the agreements between Schering and Upsher-Smith and between Schering and ESI harmed competition because the agreements had the effect of delaying the introduction of Upsher-Smith's Klor Con M20 and ESI's Micro-K20 to the market. It is undisputed that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. It is undisputed that under the June 17, 1997 Agreement, Upsher-Smith gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than five years earlier than the expiration of the '743 patent. F. 156. It is undisputed that under the handwritten settlement agreement and final settlement agreement between Schering and ESI, ESI gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than two and a half years earlier than the expiration of the '743 patent. F. 367, 372. And, it is undisputed that under license Upsher-Smith began selling Klor Con M20 on September 1, 2001. F. 94.

What is disputed is whether Upsher-Smith and ESI could have entered the market any earlier than September 1, 2001 and January 1, 2004, respectively. If Upsher-Smith and ESI could have legally entered the market prior to September 2001 and January 2004, but were paid only for delay and not as part of a legitimate settlement, as Complaint Counsel alleges, then the challenged agreements would have anticompetitive effects. Thus, to prove anticompetitive effects, Complaint Counsel must prove that better settlement agreements or litigation results would have resulted in Upsher-Smith and ESI selling their generic equivalents prior to September 1, 2001 and January 1, 2004. Complaint Counsel did not demonstrate this. Nor has Complaint Counsel brought forth evidence that the entry dates

agreed upon were "unreasonable." Thus, without sufficient evidence to prove that Upsher-Smith or ESI would have entered the market sooner than the agreements allow, Complaint Counsel failed to prove that any unlawful delay resulted from the agreements.

(i) The '743 patent operates to exclude all non-infringing products until September 5, 2006

"A patent shall be presumed valid." 35 U.S.C. § 282. This is long established law that cannot be ignored. E.g., Doddridge v. Thompson, 22 U.S. 469, 483 (1824) (a patent is presumed to be valid, until the contrary is shown); Cordis Corp. v. Medtronic, Inc. 780 F.2d 991, 995 (Fed. Cir. 1995) (patents are presumed to be valid; until invalidity is proven, the patentee should ordinarily be permitted to enjoy the fruits of his invention). But see Cardizem, 105 F. Supp. 2d at 700 (characterizing defendants' arguments as based on "erroneous presumptions" by Andrx regarding whether a generic drug would infringe the patent). However, Cardizem cites no authority to support this apparent presumption of the pending patent case and to the extent it is a presumption of invalidity or non-infringement, it is contrary to well settled precedent. A presumption of infringement or invalidity of a patent is tantamount to grafting a section onto the Hatch-Waxman Act which is clearly not there. The making of the laws is a function of our Congress.

Under its '743 patent, Schering had the legal right to exclude Upsher-Smith from the market until Upsher-Smith either proved that the '743 patent was invalid or that its product, Klor Con M20, did not infringe Schering's patent. Similarly, Schering had the legal right under its '743 patent to exclude ESI from the market until ESI either proved that the '743 patent was invalid, or that its product, Micro-K20, did not

infringe Schering's patent. Doddridge, 22 U.S. at 483; Cordis, 780 F.2d at 995. Application of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder. In re Independent Service Organizations Antitrust Litig., 203 F.3d 1322, 1326 (Fed. Cir. 2000) (court must give "due consideration to the exclusivity that inheres in the patent grant"); Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("[S]ome measure must guaranteed that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws."); Bement v. National Harrow Co., 186 U.S. 70, 88 (1902).

While Complaint Counsel acknowledges that the '743 patent gives Schering the right to exclude all infringing products, Complaint Counsel argues that antitrust laws prohibit Schering from paying Upsher-Smith and ESI to stay off the market. However, Complaint Counsel has not established that Schering paid Upsher-Smith and ESI to stay off the market because Complaint Counsel has not proved that Upsher-Smith or ESI could have even been on the market prior to the expiration of the '743 patent.

Indeed, Complaint Counsel acknowledges that it cannot prove that Upsher-Smith and ESI could have been on the market prior to September 5, 2006. In its post trial brief, Complaint Counsel states that it is impossible to reliably determine whether the Upsher-Smith and ESI products did not infringe Schering's patent or whether the alleged infringers would have prevailed in the infringement suits. CCPTB at 67-76. The evidence presented at trial confirms that the likely outcome of the patent disputes cannot reliably be predicted. Id.; F. 394. And because the outcome of the patent disputes cannot be predicted, the date on which Upsher-Smith and ESI could have entered, but for the agreements, cannot be determined. Complaint Counsel argues:

> Respondents, in advocating a test for competitive harm that cannot be done reliably, urge a rule that would effectively immunize settlements involving payments not to compete. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach patent settlements that involve payments for delayed entry, the threat of serious harm to consumers is too great, and the likelihood of deterring procompetitive agreements is too small, to justify the approach advocated by respondents.

CCPTB at 67-76

Complaint Counsel's argument may hold intellectual appeal. However, simply because, based upon the theories it advanced in this case, Complaint Counsel cannot prove whether Upsher-Smith and ESI would have come on the market earlier than September 2001 and January 2004, but for the $60 million and $15 million payments, does not relieve Complaint Counsel of its burden of proof. In Andrx Pharm., 256 F.3d 799, the court, on a motion to dismiss, held, "[o]ne can fairly infer ... that but for the Agreement, Andrx would have entered the market." Id. at 809. The court noted that Hoechst's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. Id. at 813. But in this case, after a lengthy trial, there is substantial evidence to support Respondents' defense that the agreements were legitimate agreements to settle vigorously contested patent litigation, and, in the case of Upsher-Smith, that the payment from Schering to Upsher-Smith was for Niacor-SR and the other drugs licensed from Upsher-Smith to Schering; and, in the case of ESI, that the patent litigation would not have settled without a payment from Schering to ESI and the licensing of other drugs from ESI to Schering. In the face of this substantial evidence, to agree with

Complaint Counsel would require an inference or presumption of what Complaint Counsel has not proved and would effectively shift the burden of proof to Respondents, contrary to law, as discussed supra.

Complaint Counsel, relying on United States v. Microsoft Corp., 253 F.3d 34, 79 (D.C. Cir. 2001), argues that it is not required to prove what would have happened, "but for" the challenged conduct. In Microsoft, the court noted, "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." Id. The challenge for Complaint Counsel here is much narrower. Complaint Counsel is not asked to reconstruct a hypothetical technological development, but to demonstrate that, absent Schering's payments to Upsher-Smith and ESI, Upsher-Smith and ESI would have come on the market earlier than the agreements allowed. Complaint Counsel has not done so.

Further, even though the government in Microsoft was not required to reconstruct a product's hypothetical development in a world absent the defendant's exclusionary conduct, the government was required to prove effects:

> First, to be condemned as exclusionary, a monopolist's act must have an 'anticompetitive effect' ... Second, the plaintiff, on whom the burden of proof of course rests, ... must demonstrate that the monopolist's conduct indeed has the requisite anticompetitive effect.

Microsoft, 253 F.3d at 58-59 (emphasis added). Thus, Microsoft does not relieve Complaint Counsel of proving the payments delayed entry.

(ii) Upsher-Smith and ESI would not have come on the market until the resolution of the patent infringement suits

The Hatch-Waxman Act does not provide immunity for patent infringement damages and there is no substantial evidence to demonstrate that Upsher-Smith and ESI would have entered the market before resolution of the patent infringement suits. The court, in Cardizem, accepted the plaintiffs' allegations as true, as it must on a motion to dismiss, that Andrx's generic drug would have entered the U.S. market on or about July 9, 1998, the date on which Andrx received FDA approval, but for its agreement with Hoechst. Cardizem, 105 F. Supp. 2d at 649. However, FDA approval does not mean generic entry will occur while patent disputes are unresolved. Since FDA approval of an ANDA does not shield a generic manufacturer from liability. 35 U.S.C. § 284; King Instruments Corp. v. Perego, 65 F.3d 941, 948 (Fed. Cir. 1995). The prudent practice, then, is for generic manufacturers to await the conclusion of patent litigation before marketing a product and risking financial ruin.

In this case, Upsher-Smith and ESI each received final FDA approval to market their generic versions of Schering's K-Dur 20 by November 1998 and June 1999, respectively. At the conclusion of trial, there is no credible evidence of when, if ever, ESI would have otherwise entered the market and, there is credible evidence that Upsher-Smith would not have entered the market if it was still enlangled in patent litigation, even at the end of the 30-month stay and upon FDA approval. F. 391-92. For Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "foolhardy" and potentially could have had dire consequences. F. 391-92.

c. Complaint Counsel did not prove that the payments were not to settle the infringement cases and for drugs licensed to Schering

(i) Upsher-Smith

The claims against Schering and Upsher-Smith rest upon the allegation that the $60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products. The Complaint alleges: "The $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering." Complaint ¶ 45. The Complaint alleges that the royalty payments were in fact payments to delay the introduction of Upsher-Smith's AB-rated generic to K-Dur 20. Complaint ¶ 64. Complaint Counsel have described the $60 million in royalty payments as a "veil," "disguise," "sham," and "cover." CCPTB at 2-3, 6, 8, 26, 34.

Prior to trial, Complaint Counsel acknowledged that its case would fail if it could not prove that Schering paid Upsher-Smith for delay. At a July 25, 2001 hearing, Complaint Counsel answered a question from the bench as follows:

> JUDGE: I guess I need to ask you one more question. Then are you saying the Government has to prove the payment was for delay in order to win this case?
>
> MR. KADES: Absolutely. That's what we will prove at trial ....

7/25/01 Tr. at 34. In its Post Trial Brief, Complaint Counsel reaffirmed that the Complaint requires them to prove that the $60 million was for delay rather than for a bona fide product license: "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or

the payment of fair market value in connection with 'side deals' to such an agreement." CCPTB at 43. Complaint Counsel's expert witness economist, Professor Bresnahan, agreed that a side deal at fair value did not raise competitive concerns:

> Q: All right, sir. Now, similarly had Upsher-Smith and Schering-Plough entered into an agreement that contained a side deal at fair value, same negotiation, they negotiate entry date and then they have a side licensing deal, and it contains fair market value consideration being exchanged between the parties, that would not flunk the Bresnahan test. That would not be anticompetitive according to you. Is that correct?
> A: That's right.
> Q: All right. So you don't have a problem with side agreements, as such; you want to make sure there's no net positive value flowing to the generic firm. Is that correct?
> A: That's -- that's my test, yes.

F. 172. Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." F. 172.

At trial, the evidence established that the June 17, 1997 Agreement between Schering and Upsher-Smith was a type of transaction that Complaint Counsel and their economist concede to be permissible: it was a settlement of a patent dispute by an agreement on a date of entry, with a side deal supported by fair value as determined at that time. The fact testimony at trial was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length

transaction, and that Schering's royalty payments to Upsher-Smith were payments for the products being licensed to Schering, together with certain production rights. Contemporaneous documentary evidence, such as Mr. Audibert's commercial assessment and Schering's Board Presentation, corroborated that testimony. The opinion testimony of Complaint Counsel's expert witnesses, based largely upon theory, did not impeach that unrebutted and credible fact evidence. The substantial, reliable evidence refutes Complaint Counsel's allegation that the $60 million paid to Upsher-Smith was "unrelated" to the products being licensed.

(A) The Evidence Establishes That The Niacor-SR License Was a Bona Fide Side Deal For Fair Value

Abundant evidence at trial established that the $60 million paid by Schering was fair value for Niacor-SR and the other licensed products. Upsher-Smith had for years invested heavily in Niacor-SR and in mid-1997 it appeared to be a highly promising product. F. 191-92. Start-up company Kos Pharmaceuticals had achieved a market capitalization of approximately $400 million almost entirely on the promise of its extended-release niacin product Niaspan, which, like Niacor-SR, had not yet obtained FDA approval for marketing. F. 152. Schering had a documented, pre-existing interest in an extended-release niacin product to enter the cholesterol-fighting market. F. 201-19. In the months preceding the licensing agreement with Upsher-Smith, Schering had engaged in extended negotiations with Kos over a possible U.S. co-promotion venture. F. 201-08. Schering had made a substantial written proposal to Kos, but Kos rejected it. F. 214-19. Shortly thereafter, the Niacor-SR opportunity arose. F. 138.

When the Upsher-Smith opportunity arose, Schering's James Audibert undertook a commercial assessment of Niacor-SR. F. 228. Mr. Audibert had extensive experience in the marketing of extended-release formulations, had considerable experience with cholesterol-reducing drugs, and had been involved in Schering's discussions with Kos relating to Niaspan. When he prepared his valuation of Niacor-SR, Mr. Audibert was not aware that the licensing opportunity had arisen in the context of a side deal to a patent settlement and was not aware of the amount of money that was being asked for the license rights by Upsher-Smith. F. 251. Mr. Audibert stated in his commercial assessment: "Niacor SR is expected to be launched in early 1999 with 3rd-year sales of $114 million." F.251. "In summary, Niacor SR offers a $100+ million sales opportunity for Schering-Plough." F. 254.

The other pharmaceutical products that Upsher-Smith licensed to Schering, prevalite, Klor-Con 8, 10 and M20, and pentoxifylline, also had value. According to the presentation given to Schering's Board of Directors, Schering's staff forecasted sales "to be $8 million a year in the first full year of launch, growing to $12 million a year in the second full year, and then gradually declining in year four and thereafter." F. 165.

The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. F. 163. The presentation given to Schering's Board of Directors stated that, in the course of Schering's discussions with Upsher-Smith, Upsher-Smith indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream to make up for the income that they had projected to earn from sales of Klor-Con, had they been successful in their suit. F. 163. The Board was informed that Schering had made it clear to Upsher-Smith that any such deal would have to stand on its own merit, independent of the settlement. The Board presentation provided sales projections for Niacor-SR of $100 million plus

in annual sales and showed a net present value of $225-265 million for the Niacor license. F. 164.

(B) Complaint Counsel did not meet its burden of proving that the Niacor-SR Licer e was not a bona fide side deal for fair value

(i) Dr. Levy

To prove that the $60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products, Complaint Counsel proffered Dr. Nelson L. Levy, an expert "in the field of pharmaceutical licensing and pharmaceutical valuation." F. 174. Dr. Levy testified that the $60 million payment made by Schering to Upsher-Smith cannot be considered to have been a license fee for Niacor SR and the five generic products licensed. F. 315. Dr. Levy had three bases for this opinion. First, Levy concluded that the $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, and greatly surpassed the non-contingent fees paid by Schering in other unrelated pharmaceutical transactions. F. 290, 296. Second, levy bases his conclusion on his opinion that the due diligence conducted by Schering for Niacor-SR was strikingly superficial relative to industry standards on due diligence and Schering's own due diligence practices. F. 301-03. Third, Levy bases his conclusion on his opinion that after the settlement agreement was executed, neither Schering nor Upsher-Smith undertook behavior consistent with parties who had just entered into a licensing transaction, for which Schering committed to pay $60 million. F. 315-18.

Dr. Levy's testimony is contradicted by the greater weight of the evidence. Schering presented substantial, reliable evidence demonstrating that Niacor-SR and the other licensed

products were valued at $60 million. F. 258-61. Schering presented substantial, reliable evidence demonstrating that Schering performed due diligence on Niacor-SR. F. 243-61. And, Respondents presented substantial, reliable evidence to explain Respondent's post deal conduct and attendant decisions not to pursue Niacor-SR. F. 262-74.

Furthermore, Dr. Levy's testimony is accorded less weight for three reasons. First, he performed no quantitative analysis of Niacor-SR or any of the other 5 products Schering received under the license agreement and did not consider the market value of Kos. F. 293. Second, Dr. Levy's opinions regarding value of Niacor-SR are founded in part on his conclusions regarding the safety and efficacy of Niacor-SR and his testimony demonstrated he lacked expertise in the area of cholesterol-lowering drugs and niacin. F. 308-14. Third, Dr. Levy's conclusion that the parties' post deal conduct is not behavior consistent with parties who had just entered into a licensing transaction for which Schering committed to pay $60 million is rebutted by the evidence Respondents presented on their post deal conduct and discredited because Levy did not review many of the documents reflecting the parties' communications and continued work on the licensed products. F. 315-18.

(ii) Professor Bresnahan

Complaint Counsel also offered the expert testimony of Professor Bresnahan to prove Schering's payment was not for the Niacor license. Bresnahan did not attempt to value the rights Schering obtained under the licensing agreement and did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of $225-265 million presented to Schering's Board of Directors. F. 319. Instead, Bresnahan applied a "revealed preference" test and a "market test" and analyzed the parties' incentives to opine that

the $60 million payment was not for the Niacor license. F. 320-26.

Under Bresnahan's "revealed preference" test, Bresnahan concluded that Schering's turning down of Kos' Niaspan "revealed" that Schering was not willing to make a large upfront payment for the comparable Niacor-SR product. F. 320. However, Schering demonstrated a genuine interest in Kos' sustained-release niacin product, projected substantial sales for that product, engaged in an extended dialogue with Kos, and made a serious offer incorporating a major financial commitment commensurate with the profit split under the contemplated co-promotion arrangement. F. 201-19. The substantial, reliable evidence demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. F. 217-19.

Professor Bresnahan testified that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, Niacor-SR was not highly valued enough in the marketplace to justify a non-contingent payment, and therefore the $60 million non-contingent payment made by Schering to Upsher-Smith was not for Niacor-SR. However, in June 1997, Upsher-Smith was still in active discussions with a variety of companies to market Niacor-SR. F. 325, 196. Upsher-Smith executives believed that potential European licensees were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. Because Upsher-Smith terminated its marketing efforts after signing the exclusive agreement with Schering on June 17, 1997, no conclusions as to Niacor-SR's value can be drawn from this ongoing process. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR license. F. 326. This evidence refutes the conclusion Bresnahan reached using his market test.

Professor Bresnahan also testified that Schering and Upsher-Smith had incentives to engage in a transaction trading a payment for delay and acted on those incentives. Ultimately, Professor Bresnahan was compelled to acknowledge that theoretical "incentives" hardly constitute evidence of actual improper conduct:

> Q: Professor, is it your view that if a person has an economic incentive to violate the law, that leads to the conclusion that they did so?
> A: No.

Bresnahan, Tr. 1105. These "incentives" are not legally dispositive. See, e.g., Serfeez v. Jewel Food Stores, 67 F.3d 591, 600 (7th Cir. 1995) (holding that "the presence of an economic motive is of very little probative value" and that "[t]he mere existence of mutual economic advantage, by itself, ... supplies no basis for inferring a conspiracy"). Contrary to the theory offered by Bresnahan, the record testimony from all of the participants in the negotiations provides direct evidence that the parties did not exchange money for delay. F. 322-26.

The presentation made to Schering's Board of Directors when it approved the licensing agreement reported that Upsher-Smith had expressed a desire for "an income stream to replace the income that [it] had anticipated earning if it were able successfully to defend against Key's infringement claims." F. 163. As Professor Bresnahan acknowledged, (Bresnahan, Tr. 572-573), the presentation also reported: "we informed them that any such deal should stand on its own merit independent of the settlement." F. 163. The remainder of the presentation contained a detailed discussion and financial analysis justifying the licensing opportunity on its own merit. F. 163-66. Despite Professor Bresnahan's opinion otherwise, the Schering Board presentation confirms Schering's insistence that any licensing

royalty payment to Upsher-Smith had to be independently supported by fair value.

(C) The terms of the June 17, 1997 agreement

Professor Bresnahan opined that Paragraph 11 of the June 17, 1997 agreement "links" Schering's royalty payments to the September 1, 2001 entry date. Bresnahan, Tr. 535-536. Paragraph 11 expressly describes the three payments totaling $60 million as "up-front royalty payment[s]." As evidenced by the negotiations leading up to June 17, 1997 agreement, Upsher-Smith and Schering each intended the term "royalty" to reflect that Schering would be paying for the licenses and associated production rights it was receiving from Upsher-Smith. This understanding of "royalty" comports with the common understanding of the term. See, e.g., Sierra Club, Inc. v. C.J.R., 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that "'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing Black's Law Dictionary 1330-31 (6th ed. 1979)); see also Dennis W. Carlton and Jeffrey M. Perloff, Modern Industrial Organization 528 (3d ed. 2000) ("The patent holder may produce the product (or use its new process) or license (permit) others to produce it in exchange for a payment called a royalty.") (emphasis in original). Furthermore, in Paragraph 11, the designated payor of the "royalty" payments is "SP Licensee." "SP Licensee," which is first defined in Paragraph 7, is the recipient of Upsher-Smith's licenses in Paragraphs 7 through 10. F. 156, 161. The only natural and normal reading of Paragraph 11 is that "SP Licensee" is paying "royalties" for the licenses it is receiving in Paragraphs 7 through 10.

(ii) ESI

Complaint Counsel contends that the payment from Schering Plough to ESI was only made to delay generic entry by ESI. This is not a case of a naked payment to delay an entrant who is legally ready and able to compete with Schering because Schering's patent, as discussed supra. is presumed valid. Complaint Counsel introduced a dearth of evidence about the ESI settlement agreement in its case in chief. It introduced fact evidence only in the form of deposition testimony and investigational hearing transcripts of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. Complaint Counsel offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. F. 378. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. F. 380. Thus, no evidence of fair value was offered.

As discussed supra, Complaint Counsel has the burden of proof on all violations alleged in the Complaint. Respondent Schering had no duty or requirement to offer any evidence on the ESI agreement should Complaint Counsel not do so. Complaint Counsel did not present sufficient substantial, reliable evidence to support a conclusion that ESI could have or would have entered the market before the date set on the settlement agreement. Complaint Counsel also did not present sufficient substantial, reliable evidence to support a conclusion that the Schering-ESI patent litigation would have settled without the provision for the licensing agreement for enalapril and buspirone being part of that settlement or that any payment was not for fair value. Accordingly, there is no substantial, reliable evidence to conclude that the $15 million was paid only for unlawful delay.

Moreover, it is clear that parties to a patent dispute may exchange consideration to settle this litigation. The Supreme

Court has rejected the argument that consideration renders an agreement unlawful. See Standard Oil Co. v. United States, 283 U.S. 163, 170-71 n.5 (1931) (noting that the interchange of rights and royalties in a settlement agreement "may promote rather than restrain competition").

d. Complaint Counsel has not demonstrated anticompetitive effects sufficient to shift the burden to Respondents to show procompetitive effects

Once a plaintiff has demonstrated that "great likelihood of anticompetitive effects" from agreements "can easily be ascertained," the burden shifts to a defendant to come forward with plausible procompetitive justifications. California Dental Ass'n, 526 U.S. at 770; NCAA, 468 U.S. at 113. Because Complaint Counsel has not demonstrated anticompetitive effects, analysis of Respondents' proffered justifications is not necessary.

5. Complaint Counsel Did Not Prove That The "Any Other Sustained Release Microencapsulated Potassium Chloride Tablet" Clause Restricted Competition

Complaint Counsel's position is that the Schering and Upsher-Smith settlement agreement contains additional collateral restraints which are anticompetitive. CCRB at 64. However, Complaint Counsel conceded that parties may settle patent litigation "by an agreement on a date of entry." CCPIB at 43. Any such settlement must necessarily identify the products that are the subject of the agreement – i.e. what the alleged infringer is permitted to market and what the alleged infringer is prohibited from marketing under the agreement. F. 168. This degree of specification is necessary in order to limit

the alleged infringer's ability to go to market with another infringing product under the agreement. F. 168. It is not enough just to identify the subject of the agreement as "infringing products," as the parties involved in patent litigation necessarily disagree over what does or does not infringe the patent. F. 168. Such a specification would likely lead to renewed litigation, with its attendant costs and inefficiency. Thus, an "ancillary restraint" is ordinarily required to specify the products covered in the agreement by providing an objective description of what can and cannot be marketed prior to the agreed-upon entry date.

Ancillary restraints are permitted if, and precisely because, they are "reasonably necessary" to accomplish a contract's efficiency-enhancing purposes. See Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998) (inquiring whether the challenged conduct is "reasonably necessary to achieve legitimate objectives"); Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1367-68 (3d Cir. 1996) (inquiring whether the restraint is "reasonably necessary to achieve the stated objective"); Rothery Storage, 792 F.2d at 224 ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.").

The efficiency-enhancing objectives of a patent settlement are clear. Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming."). See also Schlegal Mfg. Co. v. U.S.M. Corp., 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation ... cannot be overstated.").

Under the Schering/Upsher-Smith settlement, the scope of products subject to the September 1, 2001 entry date agreement was as narrow as was "reasonably necessary" to accomplish the

objectives of the settlement. Schering's '743 patent claims a "controlled release [microencapsulated] potassium chloride tablet ...." USX 713 at ESI EXH 000003. The Schering/Upsher-Smith settlement likewise covers any "sustained release microencapsulated potassium chloride tablet ...." F. 167. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were delayed by the ancillary restraint contained in paragraph 3, nor was such a result intended. F. 170.

Complaint Counsel's witness on this point, Bresnahan, testified that he had "no evidence" that anyone at Schering-Plough or Upsher-Smith had any product other than Klor Con M20 in mind at the time of the agreement. F. 171. With reference to paragraph 3, Bresnahan admitted that he had not examined Upsher-Smith's product pipeline between 1997 and 2001. F. 171.

Complaint Counsel's economist expert, Professor Bresnahan, expressly conceded that, assuming the settlement agreement is otherwise lawful, this provision expanding its coverage to a broader category of products is reasonable. F. 171. Accordingly, Complaint Counsel has failed to prove that the settlement agreement was broader than was "reasonably necessary" to settle the litigation.

6. Complaint Counsel Did Not Prove That the Schering/ Upsher-Smith Agreement Had the Effect of Blocking Other Potential Generic Competitors

The Complaint alleges that the June 1997 Settlement Agreement "has the effect of delaying entry into the relevant market by any other potential generic competitor," (Complaint at. ¶ 66) and specifically identifies only Andrx Corporation as the firm that "cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run." Complaint at ¶ 62.

Complaint Counsel failed to prove that any potential competitors were blocked or that the exclusivity period was manipulated or even discussed by Schering and Upsher-Smith.

The Complaint only alleges that one specific firm, Andrx, was blocked by Upsher-Smith's exclusivity. Complaint at ¶ ¶ 61-62. Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx, testified that [redacted redacted redacted] F. 395.

Executives at Upsher-Smith were not aware of any other potential competitors blocked from the market. F. 396. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. F. 397.

The 180-day exclusivity period was never discussed between Schering and Upsher-Smith during their settlement negotiations. F. 399. Nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. F. 399. Schering-Plough, similarly, acknowledges that the agreement did not make any reference to exclusivity and the subject was never even discussed. F. 399.

In the absence of proof that any other firm was blocked or that Schering and Upsher-Smith discussed the 180-day exclusivity period in their settlement negotiations, Complaint Counsel has failed to prove that the June 1997 Settlement Agreement unlawfully delayed entry by other potential generic competitors.

F. Third and Fourth Violations of the Complaint

The Third and Fourth Violations of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and

the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and ESI to monopolize the relevant markets. Complaint ¶ 70, 71. As detailed in Section D, supra, to establish monopolization or attempted monopolization, it is necessary to appraise the exclusionary power in terms of the relevant market for the product involved. Spectram Sports, 506 U.S. at 455-56. The relevant market in this case is all oral potassium supplements that a physician can prescribe to a patient in need of a potassium supplement.

1. Complaint Counsel Did Not Prove That Schering Had Monopoly Power

Monopoly power is defined "as the power to control prices in the relevant market or to exclude competitors." Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 596, n.20 (1985). The critical inquiry is whether Schering had monopoly power in the relevant market at the time it entered the challenged agreements. Bresnahan, Tr. 659-60. Complaint Counsel asserts that Schering must have had monopoly power because it otherwise would not have paid Upsher-Smith and ESI not to enter the market. This circular argument is not evidence to support a finding of monopoly power. See Interpreters, 123 F.T.C. at 642 (the fact that some members charged the agreed upon price does not necessarily mean that they have market power). Instead, monopoly power is determined through an analysis of market shares, barriers to entry and the ability of rivals to expand output in that market. Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995).

a. Market share

Complaint Counsel presented insufficient evidence on Schering's market share in the market for all oral potassium supplements. Schering's share of the market for potassium supplements between 1995 and 1999 was between 30 and 40 percent. F. 400-04. Schering's market share of less than 50 percent cannot as a matter of law support an inference of monopoly power. See, e.g., Bailey v. Allgas, Inc., 284 F.3d 1237, 1250 (11th Cir. 2002) ("A market share at or less than 50% is inadequate as a matter of law to constitute monopoly power"); Blue Cross & Blue Shield United v. Marshfield Clinic, 65 F.3d 1406, 1411(7th Cir. 1995) ("50 percent is below any accepted benchmark for inferring monopoly power from market share").

b. Lack of barriers to entry and the ability of rivals to expand output

Complaint Counsel did not prove high entry barriers into the market for all oral potassium chloride supplements. The evidence demonstrates that there were over 30 products competing as of 1997 in the potassium chloride market, all of which had entered at some point, and that a number of new competitors entered the market in recent years. F. 405-08. Absent evidence of high entry barriers, an inference of monopoly power is inappropriate. See, e.g., Western Parcel Express v. UPS, Inc., 190 F.3d 974, 977 (9th Cir. 1999) ("'A high market share, though it may ordinarily raise an inference of monopoly power, will not do so in a market with low entry barriers or other evidence of a defendant's inability to control prices or exclude competitors'") (citations omitted). Complaint Counsel did not prove the inability of other firms to expand output in the face of a price increase or output reduction by Schering. F. 405-08. When firms can rapidly expand output,

as here, an inference of monopoly power is inappropriate. See, e.g., Rebel Oil Co., 51 F.3d at 1441 (power over price "depends largely on the ability of existing firms to quickly increase their own output in response to a contraction by the defendant").

c. Pricing

Contrary to Complaint Counsel's contention, pricing above marginal cost does not establish monopoly power or market power. See [Herbert Hovenkamp and Mark A. Lemley, IP and Antitrust § 4.1c, at 4-5 thru 4-7 (Aspen Law & Business 2002)(use of marginal cost "for measuring power is very hard to make workable in the case of intellectual property"); see id. at 4-9 ("the underlying theory of intellectual property rights is that an anticipated stream of above cost prices creates the incentive to engage in research or creativity in the first place") Even if it could, Complaint Counsel failed to prove that K-Dur was sold above marginal cost for extended periods of time. The fact that someone could undersell K-Dur 20 does not prove that contention, and Complaint Counsel offered no other evidence.

Further, higher prices for a branded product do not establish monopoly power. SMS Sys. Maintenance Serv., Inc. v. Digital Equip. Corp., 188 F.3d 11, 17 (1st Cir. 1999)("In any market with some degree of product differentiation, goods of a single brand will enjoy a certain degree of uniqueness ... ,that fact, without more, does not suffice to establish that the manufacturer enjoys monopoly power in that market."), cert. denied, 528 U.S. 1188 (2000). Evidence of higher prices is ambiguous at best, and insufficient evidence of monopoly power in the absence of market analysis. Tarrant Serv. Agency v. Am. Standard, Inc., 12 F.3d 609, 615 (6th Cir. 1993) (higher prices for genuine parts was not evidence of monopoly power in market that included generic parts).

Complaint Counsel asserts that it proved monopoly power because Schering priced K-Dur 20 at an elevated price. Pricing evidence alone is not sufficient to prove monopoly power. See, e.g., Forsyth v. Humana, Inc., 114 F 3d 1467, 1476 (9th Cir. 1997)(evidence that firm "routinely charged higher prices than [competitors] while reaping high profits" did not constitute "direct evidence of market power" because there was no evidence of "restricted output"); Blue Cross & Blue Shield, 65 F.3d at 1411-12 (higher prices "may reflect a higher quality more costly to provide ... it is always treacherous to try to infer monopoly power from a high rate of return"); In re IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 981 (N.D. Cal. 1979), aff'd 698 F.2d 1377 (9th Cir. 1983) ("[The inference that a defendant that enjoys healthy profits only does so because of an unhealthy market structure is not a strong one. Good management, superior efficiency and differences in accounting provide explanations that are just as plausible, and none of those explanations is inconsistent with an effectively competitive market."). In this case, as in Forsyth, it is conceded by Complaint Counsel that at all times Schering was expanding its output of K-Dur 20. F. 409-13. Also, Schering had no ability to restrict the output of the more than 20 other firms selling "therapeutically equivalent" potassium chloride supplements. F. 408.

In addition, Complaint Counsel did not prove that Schering's pricing was at a monopoly level. Complaint Counsel's expert witness did not conduct a thorough examination of Schering's prices. Professor Bresnahan did not have a data set of Schering's prices or of competitors pricing; thus he could not compute the relative price level of K-Dur 20 to other products. F. 419 Professor Bresnahan did no study of costs so he is unable to evaluate the price increases for K-Dur 20. F. 423. Professor Bresnahan's failure to study competitive product pricing means that he cannot demonstrate that any price

increase of K-Dur 20 over a 5 year period was more or less than the price increases of competitive potassium products. F. 423.

Complaint Counsel also asserts that the failure to lose sales despite a price rise to be evidence of a monopoly. This is not sufficient evidence to prove monopoly power. The price of K-Dur 10 rose every time that the price of K-Dur 20 rose. F. 101-03. And K-Dur 10 was at all times more expensive per dose that K-Dur 20. F. 101-03. By this logic, K-Dur 10 should be a "monopoly." Both Professor Bresnahan and Dr. Addanki refused to conclude that K-Dur 10 was a separate "monopoly" unto itself. F. 101-03.

A single firm's price increase data without data from other firms is not helpful. Without knowing systematically what the other firms were doing on price, it is impossible to know the relative price of K-Dur 20 to other firm's products. Nor is it possible to discern if product costs or firm costs are rising. And net pricing considering rebates, allowances and free goods -- was also missing from this analysis. These critical aspects of Schering's K-Dur pricing were not studied by Professor Bresnahan. F. 418-29. A strong common feature of K-Dur 10 and K-Dur 20 was the heavy promotion of both products by Schering. F. 80. See Levine, 72 F.3d at 1552 (price increases do not prove actual direct effects without competitors' pricing and costs being examined).

d. Sensitivity to promotion and advertising

Professor Bresnahan conceded that Schering's advertising increased demand for potassium chloride and in particular K-Dur 20. Ray Russo testified that potassium chloride was highly sensitive to promotions. Schering outspent branded potassium competitors such as Upsher-Smith by more than 100 to 1. F. 427. These levels of advertising were tremendous relative to the size of the potassium marketplace. F. 79-80; Russo, Tr. 3418-19 ("these are relatively I think promotion-sensitive

markets .... We invested heavily in field force effort ... we had a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed K-Dur K-Dur 10 and K-Dur 20").

The fact that Schering's sales increased during the 1994 2000 period attests to the power of Schering's detailing and rebate activity. In fact, the approximately $200 million spent by Schering on rebates alone between 1995 and summer 2001 attests to the stiff competition Schering faced prior to the advent of AB-rated substitutes. F. 114-16. Schering also invested millions in promotion. F. 412.

Pharmaceutical promotions are pro-competitive, and Professor Bresnahan testified that aggressive marketing such as that practiced by Schering was not anticompetitive. Yet Professor Bresnahan made no attempt to assess the role of advertising on demand in this case or the relative strength of advertising efforts by potassium firms. Professor Addanki did so and found strong and pronounced effects from Schering's advertising. F. 411-13. Schering's executives recognized that marketing was the key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039). F.411-13.

e. K-Dur 10 sales demonstrate that K-Dur 20 was not a monopoly

K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. F. 101. Even if the 10 mEq segment were studied in isolation, K-Dur 10 had less than 9% of new prescriptions of 10 mEq strength potassium chloride. USX 626 at USL 15232 (listing more than 19 10 mEq strength potassium supplements; K-Dur 10 had 8.7% of NRx in 1996). F. 101.

Yet, despite K-Dur 10's non-monopoly status, K-Dur 10 sales performed just as Schering's K-Dur 20 performed. K-Dur 10's sales rose over time due to Schering's promotions. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. F. 101. K-Dur 10 demonstrates that avowedly non-monopoly branded products will perform in exactly the same way that K-Dur 20 performed when it is promoted.

f. Generic potassium products grew at a faster rate than K-Dur 20

Generic potassium – rather than branded potassium – grew at a faster rate than K-Dur 20, demonstrating the price sensitivity of many potassium purchasers. F. 402. Complaint Counsel assert that the sales of K-Dur 20 grew rapidly in the 1997-2000 period, implying that K-Dur 20 outsold all competing potassium despite price increases. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. F. 402. However, at the time relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. F. 402. With K-Dur 20 at 33.0% of total potassium chloride prescriptions, id., other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. F. 402.

2. Complaint Counsel Did Not Prove the Requisite Specific Intent for a Conspiracy to Monopolize the Market for Potassium Supplements

"Specific intent to monopolize is the heart of a conspiracy charge." Salco Corp. v. Gen. Motors Corp., 517 F.2d 567, 576 (10th Cir. 1975). It is more demanding than the general-intent requirement of Section 1 claims. See, e.g., Wagner v. Magellan Health Servs., Inc., 121 F. Supp. 2d 673, 681 (N.D. Ill. 2000) ("A conspiracy to monopolize under Section 2 is somewhat different than its Section 1 counterpart because of its heightened intent element, i.e., concerted action by knowing participants who have a specific intent to achieve a monopoly"). As one court recently stated, specific intent "signifies something more than willing, voluntary, and knowing participation in the illegal course of conduct that [defendant] is alleged to have pursued." In re Microsoft Corp. Antitrust Litig., 127 F. Supp. 2d 728, 731 (D. Md. 2001). Rather, "[i]t means participating in that course of conduct for the specific, shared purpose of maintaining" Schering's monopoly. Id. (citation omitted).

A mere confluence of economic interests between the parties does not establish a specific intent to monopolize. See Building Indus. Fund v. Local Union No. 3, 992 F. Supp. 162, 186 (D.D.N.Y. 1996) ("The essence of a conspiracy is not simply a commonality of interest. It involves an agreement by two or more people to accomplish a specific illegal objective"); Genetic Sys. Corp. v. Abbott Labs., 691 F. Supp. 407, 422 (D.D.C. 1988)(rejecting theory that "mutual purposes and intended effects" could satisfy specific intent standard)(citation omitted).

There is insufficient evidence to demonstrate that Upsher-Smith or Schering "specifically intended" to further Schering's alleged unlawful monopoly in the sale of K-Dur 20. Moreover, there were numerous legitimate business justifications offered

for Upsher-Smith's and Schering's conduct, including ending the expensive and acrimonious patent litigation, obtaining a date certain for entry of Upsher-Smith's generic product five years before the expiration of Schering's patent, opening the door for other generic mEq sustained-release potassium chloride supplements to enter the market, freeing up resources at Upsher-Smith for future pharmaceutical R&D and marketing of potassium products; and giving Upsher-Smith overseas distribution capability for six of its pharmaceutical products.

As the court in Microsoft explained, to establish a Section 2 conspiracy, "what plaintiffs must prove is that when confronted with Microsoft's demands, the OEM defendants stepped back and concluded that maintaining Microsoft's monopolies was a goal that they themselves desired to accomplish." Microsoft, 127 F. Supp. 2d at 731. The credible evidence demonstrates that far from seeking to further Schering's alleged monopoly, Upsher-Smith fought hard to bring its product to market and competed vigorously with Schering before, during and after the execution of the settlement agreement.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith").

2. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce

as "commerce" is defined in Section 4 of the Federal Trade Commission, 15 U.S.C. § 44.

4. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

5. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

6. Complaint Counsel bears the burden of proof of establishing each element of the violations of the Complaint.

7. The relevant geographic market for assessing the allegations of the Complaint is the United States.

8. The relevant product market for assessing the allegations of the Complaint is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement.

9. Complaint Counsel failed to prove or properly define the relevant product market.

10. Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others -- for example, by the initiation of infringement litigation - from manufacturing, using and/or selling the invention during the patent term.

11. The agreement between Schering Plough and Upsher-Smith did not unreasonably restrain competition and was not an unfair method of trade.

12. The agreement between Schering Plough and ESI did not unreasonably restrain competition and was not an unfair method of trade.

13. Schering-Plough does not have monopoly power in the relevant product market.

14. Schering-Plough did not engage in conduct to unlawfully preserve monopoly power in the relevant product market.

15. Schering-Plough did not conspire with Upsher-Smith or ESI to unlawfully preserve monopoly power in the relevant product market.

16. Complaint Counsel failed to meet its burden of proof in support of the Violations alleged in the Complaint.

17. The Complaint should be and is dismissed.

ORDER

For the reasons stated above,

IT IS ORDERED that all violations of the Complaint be, and hereby are, dismissed.

ORDERED:

/s/
D. Michael Chappell
Administrative Law Judge

Dated: June 27, 2002

APPENDIX D

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-10688-AA

SCHERING-PLOUGH CORPORATION,
UPSHER-SMITH LABORATORIES, INC.,
A MINNESOTA CORPORATION HAVING ITS PRINCIPAL
PLACE OF BUSINESS IN MINNESOTA,
PETITIONERS,

VERSUS

FEDERAL TRADE COMMISSION,
RESPONDENT.

PETITIONS FOR REVIEW OF A DECISION OF THE
FEDERAL TRADE COMMISSION

[FILED MAY 31, 2005]

Before: DUBINA and FAY, Circuit Judges, and GOLDBERG *, Judge.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no member of this panel nor other Judge in regular active service on the Court

having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 35-5), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/s/ Peter T. Fay
United States Circuit Judge

* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

STATUTORY APPENDIX

1. 15 U.S.C. 1 provides:

> Trusts, etc., in restraint of trade illegal; penalty
>
> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

2. 15 U.S.C. 45 provides in pertinent part:

> Unfair methods of competition unlawful; prevention by Commission
>
> (a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade
>
> (1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.
>
> (2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air

carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. § 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

* * * * *

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the

method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set

aside, in whole or in part. The Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph[1] (2) not later than 120 days after the date of the filing of such request.

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of

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[1] So in original. Probably should be "clause".

the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of Title 28.

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

* * * * *

3. 21 U.S.C. 355 provides in pertinent part:

New Drugs

* * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2) (A) An abbreviated application for a new drug shall contain–

* * * * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section–

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the

new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

* * * * *

(5) (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

* * * * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph

(2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that–

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on–

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed–

(aa) if the judgment of the district court is appealed, the approval shall be made effective on–

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval

shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

* * * * *

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of–

(aa) the earlier of the date that is–

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described

in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

* * * * *

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

* * * * *

4. 35 U.S.C. 271 provides in pertinent part:

Infringement of Patent

* * * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit–

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)–

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

5. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) provides in pertinent part:

* * * * *

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.–

(1) REQUIREMENT.–A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.–An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding–

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and

Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

* * * * *

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

* * * * *

SEC. 1115. ENFORCEMENT.

(a) CIVIL PENALTY.–Any brand name drug company or generic drug applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.–If any brand name drug company or generic drug applicant fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 1116. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle–

(1) may define the terms used in this subtitle;

(2) may exempt classes of persons or agreements from the requirements of this subtitle; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

SEC. 1118. EFFECTIVE DATE.

This subtitle shall–

(1) take effect 30 days after the date of the enactment of this Act; and

(2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of the enactment of this Act.

* * * * *

(13)

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No. 05-273

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v.

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

SUPPLEMENTAL BRIEF FOR THE PETITIONER

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SUPPLEMENTAL BRIEF FOR THE PETITIONER

This supplemental brief is filed pursuant to Rule 15.8 of the Rules of this Court, to address the arguments presented by the United States in its brief as amicus curiae ("U.S. Br."). The United States acknowledges many of the key factors that support the grant of certiorari: that the antitrust treatment of patent settlements involving "reverse" or exclusion payments is an important and unsettled issue (U.S. Br. 8, 19, 20); that settlements involving such payments pose risks for competition and consumers (*id.* at 8); that such payments "can be a device for the sharing of monopoly rents" (*id.* at 9); and that the potential for consumer harm is particularly acute in cases involving pharmaceuticals subject to the Hatch-Waxman Act, where settlements can delay the marketing of low-cost generic drugs for many years (*id.* at 9-10).

Despite the acknowledged importance of the legal issue presented by the petition, the United States asks that the Court await a hypothetically more suitable vehicle for review. The reasons it advances, however, fail to refute the Commission's showing that plenary review is both appropriate and much needed. In its observations on the merits, the United States fails to appreciate the extent to which the ruling below will place pharmaceutical patent settlements beyond antitrust scrutiny, or the fundamental inconsistency between such a rule of law and the policies of Congress, as set forth in the Hatch-Waxman Act. The United States also overstates the difficulty this Court would have in reversing a court of appeals ruling that wholly disregards the proper standard of review of administrative factfinding.

Most importantly, however, the United States does not address the urgent practical reasons why immediate review is needed. As the Commission and several amici have explained, the economic impact of the ruling below on consumers of prescription drugs – including the States – is staggering. See Pet. 24-25; States Br. 11-14; AARP Br. 9-14; Waxman Br. 2-3; NACDS Br. 4-6. Indeed, billions of dollars in added prescription drug costs *annually* are at stake. See Pet. 25 & n.23. The decision below has "opened a Pandora's box" of anticompetitive settlements between brands and generic competitors.[1] Although there was a five-year lull in pay-offs to potential competitors after the Commission commenced enforcement

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[1] Stephanie Kirchgaessner and Patti Waldmeir, *Drug patent payoffs bring a scrutiny of side-effects*, Financial Times UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting Cowen & Co. analyst's report on decision below). The same article points out "how damaging" a single settlement in this area can be, noting that American consumers saved $2.5 billion due to the early entry of a generic form of the drug Prozac, but only after the branded company refused to pay off the generic challenger, due in part to antitrust concerns, and a court ruled in the generic's favor.

actions aimed at exclusion-payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.[2] Harm is very likely ongoing each day that the decision below prevails.

1. In arguing that immediate review is not needed, the United States misreads the court of appeals' ruling, supposing that the ruling would permit an antitrust plaintiff to establish liability on the basis of a *post hoc*, "direct" evaluation of the patent litigation merits. See U.S. Br. 11-12, 17-19. We have explained previously why it is apparent that the court of appeals' reasoning extends to any non-"sham" assertion of patent coverage, within the nominal term of the patent. See Pet. 14-16; Pet. Reply 2-3. It is incongruous to suppose, as the United States apparently does, that the court of appeals is prepared to accept a rule that liability may be based on a "limited examination" of the patent merits, U.S. Br. 17, 11 n.1, when that court has rejected a subsequent authoritative adjudication of patent invalidity as a basis for condemning an exclusion-payment settlement. See *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294, 1306-1307, 1309 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).[3] Other courts have understood the ruling below to demand only an inquiry into the nominal reach of the patent, and not an assessment of the

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[2] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 - A Report by the Bureau of Competition*, at 3, <www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

[3] Moreover, the United States, like the court of appeals, further errs in supposing that the administrative law judge ("ALJ") assessed the strength of the patent. U.S. Br. 18. On the contrary, the ALJ disavowed any such analysis, concluding that "[o]pinions on the merits of cases that settle before the court decides them can never be tested." Pet. App. 265a.

likelihood that the patent-holder could successfully effect exclusion through patent litigation. See, *e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("*Cipro*") (the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity"). Indeed, as the United States acknowledges, the Second Circuit's ruling in *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) ("*Tamoxifen*"), expressly embraces the "sham" standard, while also expressly following the ruling below. U.S. Br. 19; see 429 F.3d at 396-397.

Furthermore, any suggestion in the United States' brief that a "mini-trial" on the patent merits is a required part of every antitrust analysis conflicts with rule of reason principles, and only adds to the array of conflicting positions on the issue presented. As the Commission explained in its opinion, such a *post hoc* review may be appropriate in some circumstances – most particularly in private actions where damages are at issue – but it was neither necessary nor helpful in the present case. See Pet. App. 80a-87a. A key drawback to such an approach – discussed in the Commission's opinion, but not addressed in the United States' brief – is that it places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal. See Pet. App. 86a-87a. More fundamentally, such an after-the-fact assessment is simply unnecessary where, as here, the contemporaneous actions of knowledgeable economic actors – particularly the generic firms' refusal to defer entry absent substantial payments by the patent-holder – provide a more reliable indication of the strength of the patent, and of the exclusionary nature of

the agreement.[4] See Pet. App. 85a-86a. Imposition of a rigid requirement that a "direct" assessment of the strength of the patent is necessary in all such cases would be at odds with this Court's teachings that the Commission is entitled to rely upon "common sense and economic theory," *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 456 (1986), and that antitrust analysis under the rule of reason is a flexible enterprise, requiring "an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint," *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999).

Far from supporting the denial of review in the present case, the United States' proffer of yet another approach to this difficult issue simply adds to the disarray among the lower courts – and the state and federal authorities that enforce the antitrust laws – that warrants this Court's attention.

2. The ruling below not only conflicts with basic antitrust principles, but it vitiates specific congressional policies of the Hatch-Waxman Act. See Pet. 3-6, 20-22. The United States makes the same error as the court below when it concludes that the profitability of collusive patent settlements under the Act provides "unique justifications" for such collusion. U.S. Br. 10; see *id.* at 7 (exclusion-payment settlements are a "'natural by-product of the Hatch-Waxman process'" (quoting Pet. App. 32a)). The United States indicates that exclusion payments may be necessary to redress "gross disparities in the litigants' respective risks," occasioned by the generics' ability to "force" a branded company into litigation prior to "actual infringement." U.S. Br. 10. But Congress itself has spoken to the

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[4] In the present case, moreover, the Commission found substantial *additional* evidence of the parties' expectations regarding likely generic entry. Pet. App. 68a-70a. Further, respondents failed to adduce evidence to rebut complaint counsel's prima facie case, such as benefits to a "cash starved" generic company or the effects of differing assessments and degrees of risk aversion by the parties. Pet. App. 89a-90a.

"conflicting policy considerations" the United States discusses. *Ibid.* It is the prerogative of Congress to define the act of infringement that gives rise to an infringement suit, to determine whether and how to encourage the early litigation of weak patent claims, and otherwise to decide how to facilitate the early market entry of generic drugs. The court of appeals' decision, reflecting *its* view of "policy," Pet. App. 35a, flouts that of Congress itself. See Pet. 4-5; 20-22; see also Waxman Br. A proper respect for the powers of Congress ought to compel at least a full examination of the arguments in this case.

In any event, the United States is mistaken in supposing that a branded company may be "forced" into such litigation. The choice remains with the branded company whether to take advantage of the 30-month stay that comes with prompt initiation of litigation, or instead shift the risk to the generic by waiting to sue until the generic has made the difficult choice of entering the market despite the risk of damages. See Pet. 3-4; see also *Teva Pharms. USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) (denying standing of generic applicant to compel adjudication of patent dispute by means of a declaratory judgment action, where the branded company has declined to commence an infringement action). Regardless of when the branded company elects to sue, however, both sides have much at stake, in terms of losses of anticipated future revenues, and may seek to limit those losses by means of settlement. As shown by industry experience during the years prior to the court of appeals' ruling in this case, litigants in such cases were in fact able to settle cases, *without* exclusion payments, by other means – most notably by compromising on entry dates.[5] See Pet. 22 (citing FTC report

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[5] As the Commission has noted (Pet. 18), a settlement that contains the parties' compromise on an entry date without cash payments presumably would reflect the parties' own assessment of the strength of the patent, and thus does not normally raise antitrust concerns. See Pet. App. 75a-76a.

on FY 2004 Hatch-Waxman settlements).* Thus, although the United States is correct to be concerned that an overly stringent rule might "frustrate[]" the public policy favoring settlements, U.S. Br. 10-11, the history of patent settlements in the pharmaceutical industry shows that the Commission's rule of reason analysis, drawing reasonable inferences from the existence of substantial exclusion payments, has not chilled legitimate settlements.

3. a. The United States also errs in suggesting that factual complexity or "unusual circumstances" make this case an unsuitable vehicle for consideration of the important antitrust issues presented. U.S. Br. 14, 15. As to the factual issue regarding the agreement between Schering and Upsher, the United States overstates the difficulty of this Court's task. Although the underlying evidentiary record is substantial, the Commission's opinion carefully recounts its review of the record evidence and its reasons for arriving at findings different from those of the ALJ. See, *e.g.*, Pet. App. 92a-96a, 108a-110a, 130a-133a. One need look no further than these passages and the corresponding ALJ findings to recognize that the Commission's findings were well grounded in the record, and, accordingly, that the court of appeals' ruling at best represents the choice of one possible set of inferences over that of the Commission, on the basis of a mixed evidentiary record. Such appellate factfinding is flatly contrary to this Court's directives. See *FTC* v. *Indiana Federation of Dentists*, 476 U.S. at 454 (reviewing court may not choose among "uncertain and conflicting inferences") (citation omitted).

The court of appeals' rote utterance of correct legal standards (Pet. App. 10a-11a) should not insulate its errors from

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* FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by The Bureau of Competition*, <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

review. Just this Term, in a case arising in another context in which Congress has prescribed deferential review of a designated factfinder, the Court reversed a court of appeals that had "recited the proper standard of review," but "improperly substituted its evaluation of the record for that of the [lower tribunal]." *Rice* v. *Collins*, 126 S. Ct. 969, 971 (2006) (habeas corpus review under 28 U.S.C. 2254). The present court of appeals' egregious misapplication of "settled rules that limit its role and authority," *id.* at 972, similarly warrants this Court's attention, and certainly should not preclude review of the vitally important underlying issue.

b. In any event, the agreement between Schering and ESI continues to provide an independent basis for this Court's review of Question 1 of the petition. The United States draws precisely the wrong conclusion from the fact that $10 million of Schering's payment to ESI was contingent on FDA approval of ESI's generic drug, citing that undisputed fact as somehow a complicating factor in analyzing the reverse-payment settlement. U.S. Br. 15. The conditioning of this payment on FDA approval, however, corroborates the conclusion that the $10 million was indeed an *exclusionary* payment: it was triggered only as ESI became a more imminent competitive threat, and was therefore a naked payment to stay out of the market. The contingent nature of the payment is an illuminating factor in this Court's understanding of the reverse-payment dynamic, rather than a complicating one. Similarly, the fact that the ESI settlement resulted from a court-assisted mediation process (U.S. Br. 14-15) does not militate against review, because the court of appeals' broad ruling applies to all exclusion-payment settlements, no matter how they are reached.

4. Although it is always possible for an issue dividing the lower courts to become more clearly defined through further litigation, there is substantial tension in the approaches adopted by the lower courts to date. The court below, now joined by the Second Circuit, condones pharmaceutical patent settlements as

long as exclusion is within the nominal scope of non-"sham" patent claims. See Pet. Reply 2-3; *Tamoxifen*, 429 F.3d at 396-397. By contrast, the Sixth Circuit has adopted a line of reasoning that appears to lead in a very different direction, recognizing the potential of such agreements "to bolster the patent's effectiveness" by "paying the only potential competitor * * * to stay out of the market." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied*, 543 U.S. 949 (2004); see also *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 809, 813 (D.C. Cir. 2001) (recognizing, in rejecting arguments for dismissal of antitrust claim for supposed lack of injury, that payment to generic may support inference that it was quid pro quo for delayed entry). Although certain aspects of the *Cardizem* ruling made it an unsuitable vehicle for review (U.S. Br. 17; Pet. 23 n.18), it and the present case nevertheless reflect an uncertainty in the law that can only be addressed by this Court.

Nor is there any reason to believe that pending or future private litigation will afford this Court a superior and timely opportunity to address this issue. Although the United States points to the possibility of review in the *Cipro* litigation (U.S. Br. 16), the Second Circuit has already staked out a position parallel to that of the court of appeals in the present case, as discussed above. In the absence of en banc reconsideration in the *Tamoxifen* case, the pending appeal in *Cipro* is unlikely to shed further light on the issue.[7]

Further, this Court's exercise of its broad discretion to grant certiorari is guided by many factors, including the importance of a lower court ruling to the Nation's economy. See, *e.g.*, *Texaco Inc.* v. *Dagher*, 126 S. Ct. 1276, 1279 (2006). The United States and the Commission recently advised the Court

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[7] In light of the pendency of the petition for rehearing in *Tamoxifen*, and the possibility of the filing of a petition for certiorari in that case, the Court may wish to hold the present case pending final resolution of that case.

to grant certiorari in another antitrust case, despite the lack of a "square * * * conflict" in the lower courts, because it presents an important antitrust issue "in the context of a complete factual record," and because the court of appeals ruling "threatens to chill procompetitive conduct" by firms subject to suit in the Ninth Circuit. See Brief for the United States as Amicus Curiae, *Weyerhaeuser Co.* v. *Ross-Simmons Hardwood Lumber Co., Inc.*, No. 05-381, at 19-20 & n.13 (filed May 26, 2006). The present ruling also follows a thorough adjudication, and insulates imminent anticompetitive conduct from Commission enforcement actions nationwide. See Pet. 23-24. Review is even more urgently needed in the present case, to protect consumers of prescription drugs from extensive economic injury.

* * * * *

For the foregoing reasons and those stated in our petition and reply, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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IN THE

Supreme Court of the United States

No. 05-273

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

The promotion of early market entry by low-cost generic drugs in competition with branded drugs is a national policy of critical importance. Respondents do not deny the major economic implications of delayed generic drug entry, not only to individual consumers but also to the States and other health care payors. Nor do respondents seriously dispute that Congress has repeatedly and expressly sought to promote early challenges to patent claims that stand in the way of such entry. Instead, they attempt to brush off the ruling below as a case-specific implementation of accepted principles, dependent on factual findings. In fact, however, the court of appeals fashioned a rule of law "reflect[ing]" its own notions of "policy," Pet. App. 35a, a rule that ignores basic antitrust principles, actively assails the congressional policies of the Hatch-Wax-

man Act, and provides pharmaceutical companies with a road-map for sharing monopoly profits rather than competing. Given the number of pending patent cases involving generic drug challengers and potential consumer injury in the billions if patent holders can simply pay these challengers to go away, this Court's consideration of these issues is urgently needed.

1. a. This case puts into sharp focus an issue that is fundamental to antitrust doctrine in the Hatch-Waxman context: whether a branded drug seller can buy protection from potential generic competition so long as the competition excluded falls within the nominal scope of a non-sham patent claim. Respondents attempt to slough off the legal significance of the issue by emphasizing the "common ground" on which "*all agree*," Resp. Br. 3, 16, and characterizing the Commission's ruling as a flawed "implementation" of an agreed framework. *Id.* at 19-20. In reality, however, the court of appeals and the Commission have articulated and applied dramatically different rules of law, which have dramatically different consequences for competition and consumers.

As we have explained, Pet. 14-16, the court of appeals' ruling here must be understood in conjunction with its earlier decision in *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, No. 03-1175 (Oct. 12, 2004). In *Valley Drug*, the court of appeals ruled (correctly) that the reasonableness of any settlement agreement must be judged "at the time [it is] entered into," and, accordingly, ruled that a subsequent adjudication against the patent claims did not advance the antitrust claim. 344 F.3d at 1306, 1309. Thus, respondents' suggestion that a *post hoc* inquiry into the patent merits would satisfy the court of appeals, Resp. Br. 12, 18-19, is disingenuous, because *Valley Drug* precludes a conclusion of liability on that basis.

The present ruling goes beyond *Valley Drug* and completes the barrier against antitrust liability for patent settlements. *Valley Drug* held that a plaintiff cannot rely on a *post hoc*

inquiry into the merits, and the ruling below proceeds on the flatly erroneous premise that there is a presumption of both patent validity *and* infringement. These rulings together effectively immunize all payments to delay generic competition, provided the delay does not extend beyond the nominal scope of an untested patent, unless the patent claim is an obvious "sham," Pet. App. 20a, or the patentee "knew" that its claim was without merit, 344 F.3d at 1309.

b. The Commission, by contrast, recognized that allowing a branded drug company to "buy off" a would-be generic entrant is contrary to both basic antitrust principles and the clear directives of the Hatch-Waxman Act, even if the generic's prospects for successful entry are uncertain.[1] Contrary to the assertions of *amicus* Bayer Corporation, Br. 13-20, the Commission's antitrust analysis took account of the uncertainties inherent in patent litigation, and there was nothing novel about doing so. As the Commission pointed out,

> The uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition * * *.

Pet. App. 84a n.62. This holding derives from basic antitrust principles this Court has repeatedly recognized. See Pet. 15 (citing, *inter alia*, *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46

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[1] The legal analysis of the court below is also at odds with that of the Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004). See Pet. 23; States Br. 7 ("The Sixth Circuit and the Eleventh Circuit cannot both be correct"). The extent of the inconsistency between the Sixth and Eleventh Circuits was far less apparent before the ruling in this case, which completed the barrier against antitrust challenges to patent settlements. *Cf.* Resp. Br. 20; Bayer Br. 7-8.

(1990) (per curiam), and *United States* v. *Griffith*, 334 U.S. 100 (1948)). The Commission's ruling is not based on some theory of a "consumer property right" in such uncertainties, Bayer Br. 14, but on the common-sense notion that it is unlawful for a competitor to buy off threatened, albeit uncertain, competition.

Respondents and *amicus* are wrong, in any event, to deny the public interest in the judicial resolution of disputed patent claims. In *United States* v. *Singer Mfg. Co.*, 374 U.S. 174 (1963), Justice White explained that a patent interference settlement that was part of the conduct the Court held unlawful harmed the public interest because it prevented the possibility that the patent would be invalidated altogether. *Id.* at 199-200 (White, J., concurring). As he further observed, "[t]he patent laws do not authorize, and the Sherman Act does not permit, such agreements between business rivals to encroach upon the public domain and usurp it to themselves." *Id.* at 200.[2]

The Commission's holding was not only compelled by antitrust principles, but is also essential to fulfill the policies of the Hatch-Waxman Act. As we have explained, that statute was enacted to encourage the early resolution of disputed pharmaceutical patent claims, and Congress amended it in 2003 to provide specifically for antitrust review of settlements like the present one by the Commission and the Department of Justice. See Pet. 20-22; Waxman Br. 2-10. The opinion below is overtly hostile to those statutory goals. The court bemoans the "caustic environment" of patent litigation and finds shocking the prospect that a statutory scheme designed to promote chal-

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[2] See also *Blonder-Tongue Labs., Inc.* v. *Univ. of Illinois Found.*, 402 U.S. 313, 343 (1971) ("The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope") (quoting *Precision Instrument Mfg. Co.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

lenges to patent claims might actually "cost Schering its patent." Pet. App. 33a, 31a.

c. Respondents distort the Commission's ruling by contending that it amounts to a "*per se*" rule based on a "theory that payments [by the patentee] render settlements anticompetitive." Resp. Br. 11, 19-20. In fact, the Commission looked to the existence of these payments not as an evil in itself or as *per se* improper, but as a reflection of the parties' own assessment of their respective prospects in patent litigation. ESI, for example, was *not* willing to trade off its chance of success in litigation for guaranteed entry in January 2004, but it *was* willing to accept that entry date plus $15 million (including $5 million purportedly for attorneys' fees). Pet. 7. As the Commission recognized, the parties are in a better position to understand the strengths and weaknesses of their patent claims, and such actions – if unexplained – provide a far more reliable gauge of the real strength of the patent claims than second-guessing by an antitrust tribunal.[3] See Pet. App. 80a-87a. The Commission declined respondents' invitation to adjudicate the patent merits as part of the antitrust analysis, because contemporaneous actions are far more probative than *post hoc* rationalizations.[4]

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[3] In any event, respondents are wrong in asserting that their evidence regarding the strength of Schering's patent claim was unrebutted, and that generics "would have been excluded" for the full patent term in the absence of settlement. Resp. Br. 5. The issue was contested at trial, and the ALJ determined it was not possible to predict the outcome of the patent litigations reliably. Pet. App. 264a-265a. Moreover, as shown previously, contemporaneous projections by respondents themselves presumed that generic entry would in fact occur well in advance of patent expiration. Pet. 8 n.4.

[4] The Commission also pointed out additional reasons why an *ex post* inquiry into the patent merits was neither necessary nor helpful, including the inherent unreliability of such inquiries and the prospect that such inquiries could "ultimately have a chilling effect on the efficient settlement of patent litigation." Pet. App. 81a; see *id.* at 80a-87a.

The Commission made clear, however, that its rule of reason analysis would permit a patent holder to justify settlements with payments that would promote efficiencies or other procompetitive effects. Pet. App. 61a-62a, 87a-91a. Respondents made no such showing, *ibid.*, and are understandably silent on this issue in their brief in opposition.

Amicus Bayer Corporation attacks the strawman of a "'better settlement' theory," Bayer Br. 9-13, on which the Commission did not rely. While the Commission used a hypothetical cashless settlement as a benchmark for the expected outcome of litigation, Pet. App. 75a-76a (see Pet. 18-19), the ultimate focus of its inquiry was simply whether Schering's payments "resulted in a greater delay than would otherwise have occurred," Pet. App. 75a, whether the "otherwise" was an alternative settlement or the expected value of continued litigation. The failure of the court of appeals to discuss these principles, Bayer Br. 15, simply reflects the court's misunderstanding of the antitrust and patent principles at stake in this case.

2. Respondents attempt to forestall this Court's review of the important substantive issues presented by arguing that the analysis of the Upsher agreement turns on factual issues not worthy of this Court's attention and that the ESI agreement can be dismissed as unimportant. Resp. Br. 1-2, 12-16. Neither assertion bears scrutiny.

a. Respondents ignore the most salient aspect of the standard of review issue posed in Question 2 – *i.e.*, that it is the Commission's findings, not the administrative law judge's, that are to be tested against the record and, if supported by substantial evidence, accorded due deference by the court of appeals. *Consolo* v. *Federal Maritime Comm'n*, 383 U.S. 607, 618-620 (1966) (that substantial evidence may support a conclusion contrary to the commission's is no basis for overturning the latter); *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 496 (1951) (the substantial evidence "standard is not modified in any way when the [agency] and its examiner disagree"). The

court of appeals' improper reliance on the ALJ's findings is pivotal to its analysis. See Pet. App. 25a-26a.

In an apparent effort to lend more weight to the ALJ's findings and diminish those of the Commission, respondents claim that the factual issue reduces to a simple arithmetic comparison of projected sales and money paid for patent licences. Resp. Br. 6-8. The relevant question, however, which the Commission analyzed in 40 pages of findings, was whether the totality of the evidence indicated that Schering's unconditional, up-front payment *really was* a royalty payment, or was instead in large part a payment for the exclusion of competition. See Pet. App. 92a-141a.[5] To the extent there was a "credibility" issue here, it was "not solely a function of the witness's demeanor but also of that testimony's inherent plausibility," in light of the context. See Breyer, Stewart, Sunstein & Spitzer, *Administrative Law and Regulatory Policy* (4th ed. 1999), at 222. The Commission had the responsibility and prerogative to make that assessment.

We recognize that the Court is generally reluctant to correct errors in the application of the substantial evidence test, but the error here is so blatant and the consequences so serious that review is warranted. See *Universal Camera*, 340 U.S. at 491 (Court will intervene where court of appeals has "grossly misapplied" test); accord *FTC* v. *Indiana Federation of*

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[5] There is, therefore, no inconsistency between the Commission's opinion and the statements elsewhere of its author, Commissioner Thomas B. Leary, regarding the difficulty of evaluating intellectual property. See Resp. Br. 10-11 n.7, 16 n.9. In fact, in both the article and the opinion, Commissioner Leary listed exactly the same factors as relevant when assessing whether a side deal amounts to an exclusion payment, including negotiation history, other offers for the intellectual property at issue or property with similar attributes, evidence based on subsequent events, and the structure of the payment terms. See Pet. App. 93a-139a; Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001), at 6, available at: http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm.

Dentists, 476 U.S. 447, 454 (1986). This Court need not canvass the record itself and resolve the ultimate issue whether substantial evidence supported the Commission's findings, but may remand to the court of appeals for review of the factual issues under a proper standard.

b. In any event, no such factual dispute exists with regard to the ESI agreement, which the Commission assessed under the same principles as those it applied to the Upsher agreement. As respondents concede, Schering's $10 million payment that was contingent on FDA approval of ESI's competitive generic product had no purpose other than to induce ESI to enter into the agreement in which its market entry was precluded until 2004. Resp. Br. 6. Even assuming that Schering was responding to the pressures of the magistrate-supervised mediation, that does not change the fact that the settlement was a private agreement, entered into by sophisticated business parties for their mutual and substantial benefit, and was *not* approved by any court.

3. Finally, respondents make no serious effort to dispute the showings of the Commission and several *amici* about the staggering economic importance of the availability of generic drugs. Indeed, they acknowledge that "generic entry will bring lower prices." Resp. Br. 17 n.10; *cf.* Pet. 24-25; States Br. 11-14; AARP Br. 9-14; Waxman Br. 2-3; NACDS Br. 4-6. Respondents' attempts to minimize the impact of the present case, Resp. Br. 20-23, ignore the basic fact that whatever "*in terrorem*" effect on anticompetitive settlements the Commission's enforcement program may have had is vitiated by the ruling below. Respondents suggest enforcement under Section 5(m) of the FTC Act, 15 U.S.C. 45(m), but actions under that provision require an existing final Commission order, such as the one vacated here. Equally quixotic is respondents' supposition that a Commission order against an exclusionary settlement could pass muster in the Eleventh Circuit – to which any pharmaceutical company that does business there could appeal.

See 15 U.S.C. 45(c). As explained above, the combined effect of the court of appeals' decisions here and in *Valley Drug* precludes meaningful Commission review of patent settlements. See Pet. 21.[6]

* * * * *

For the foregoing reasons and those stated in our petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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[6] That court's recent ruling in *Andrx Pharms., Inc.* v. *Elan Corp., PLC*, 421 F.3d 1227 (11th Cir. 2005), does nothing to ameliorate the effects of its prior rulings, for it is premised on the acceptance (at the dismissal stage) of allegations that the patentee and generic entrant conspired to use the generic's 180-day exclusivity period to block other competitors "from ever marketing a generic" version of the drug in question. 421 F.3d at 1235.

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FEDERAL TRADE COMMISSION, PETITIONER

v.

SCHERING-PLOUGH CORPORATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

2. Whether the court of appeals erred in concluding that "substantial evidence" did not support the Federal Trade Commission's factual finding that a payment from a patent holder to an allegedly infringing generic manufacturer was consideration for the generic manufacturer's delayed entry into the market rather than a separate royalty for a license concerning a different product.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied. The decision below does not conflict with any decisions of this Court or the courts of appeals, and the only important but unsettled issues of federal law that are raised by the petition are not well presented in this case.

STATEMENT

Respondent Schering-Plough Corporation (Schering), a pharmaceutical company, produces and markets a brand-name drug, K-Dur 20, for treating high blood pressure and congestive heart disease. K-Dur 20 contains unpatented potassium chloride encapsulated in an extended release coating that is protected by Schering's United States patent number

4,863,743 (the '743 patent), which expires on September 5, 2006. Pet. App. 2a-3a. Schering sued two of its competitors for proposing to market generic drugs that allegedly would infringe that patent. Thereafter, the parties to those respective suits entered into settlement agreements providing that (1) the defendants would be free to market generic versions of K-Dur 20 as of specified future dates that were earlier than the expiration of the '743 patent, and (2) Schering would make substantial payments to the defendants. The Federal Trade Commission (FTC or Commission) challenged the settlements and held that they violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45. The court of appeals vacated the FTC's order. Pet. App. 1a-35a.

1. The two settlements at issue in this case arose in the statutory context created by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug (a "brand name" drug) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved, a firm seeking to market a generic version of that drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. 355(j). The FDA may approve the marketing of a generic drug before the expiration of a patent relating to the brand name drug if the applicant makes a "paragraph IV certification" that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. 355(j)(2)(A)(vii)(IV). If the patent holder files a patent infringement suit within 45 days after receiving notification

of such a certification, however, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). The first company to file an ANDA with a paragraph IV certification relating to a particular brand name drug is granted the exclusive right to market a generic version until 180 days after the earlier of two dates: when it begins commercial marketing or when a court holds the patent invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv).

2. In 1995, two competitors, Upsher-Smith Laboratories (Upsher) and ESI Lederle, Inc. (ESI), separately filed ANDAs that contained paragraph IV certifications and sought FDA approval to market generic versions of K-Dur-20. Pet. App. 3a-4a & n. 2, 6a n.5. Schering responded by suing each company for patent infringement. In 1997, Schering and Upsher engaged in settlement negotiations, and agreed that Upsher's generic could be marketed on September 1, 2001, five years before expiration of the '743 patent. Upsher, however, "insisted upon its need for cash prior to the agreed entry date," while Schering stated that it "refused to pay Upsher to simply 'stay off the market.'" *Id.* at 4a; see *id.* at 100a, 188a. Ultimately, the parties negotiated, as part of the settlement, an exclusive license under which Schering paid $60 million to Upsher and received the exclusive right to market several Upsher products outside North America, including Upsher's Niacor-SR (Niacor), a cholesterol-reducing drug. *Id.* at 195a-197a.

In the ESI litigation, the court appointed a magistrate judge to supervise mediation. More than a year later, in December 1997, under what the FTC termed "intense, and perhaps unseemly, judicial pressure to settle the patent litigation," Pet. App. 144a, Schering offered to permit ESI to market its generic on January 1, 2004, more than two years before

expiration of the '743 patent. ESI agreed on the date but insisted on a payment. At the magistrate judge's suggestion, Schering then offered $5 million in legal fees. ESI insisted on more, and the magistrate judge and Schering devised a settlement that included an additional payment of $10 million conditioned on ESI's receiving FDA approval for its generic drug by a specified date. *Id.* at 7a.

3. In March 2001, the FTC issued an administrative complaint alleging that the two agreements unreasonably restrained competition in violation of Section 5 of the FTC Act, 15 U.S.C. 45. Pet. App. 48a-49a, 145a; Complaint ¶¶ 68, 69, at 9, *Schering-Plough Corp.*, Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003). The core allegation was that Schering's cash payments induced Upsher and ESI "to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher[] nor ESI would have agreed to delay its entry for so long." Complaint ¶ 64, at 8-9.

a. After a two-month administrative trial, the administrative law judge (ALJ) concluded that the challenged agreements "did not unreasonably restrain competition" and dismissed the complaint. Pet. App. 340a. The ALJ found that Complaint Counsel had failed to prove that either payment by Schering was made in exchange for delayed entry. The ALJ determined that the evidence showed that the Upsher licensing agreement was a bona fide agreement and that the $60 million payment from Schering to Upsher represented a fair value for the licenses. *Id.* at 316a-324a. The ALJ also found no "substantial, reliable evidence to conclude that the $15 million was paid [to ESI] only for unlawful delay." *Id.* at 325a.

The ALJ also reasoned that, in order to establish that the settlements had the alleged anticompetitive effect, Complaint Counsel needed to "prove that better settlement agreements or litigation results would have resulted in Upsher[] and ESI

selling their generic equivalents prior to September 1, 2001 and January 1, 2004," *i.e.*, the entry dates agreed upon in the two settlements. Pet. App. 310a. Because Complaint Counsel could not prove that, absent the settlement agreements, either company would have entered the market before the expiration of Schering's patent, *id.* at 310a-312a, 315a, the ALJ concluded that Complaint Counsel had failed to meet its burden of proof, *id.* at 313a-314a.

b. The Commission reversed. Pet. App. 36a-153a. With respect to the Upsher agreement, the FTC found that "there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses." *Id.* at 141a. The FTC therefore concluded that "Schering did in fact pay Upsher for delayed entry." *Ibid.* Likewise, because it found no other satisfactory explanation for the $10 million payment from Schering to ESI, the FTC concluded that the ESI payment was in exchange for delayed entry. *Id.* at 144a-145a; see *id.* at 142a n.101.

The FTC explained that the question whether the payments violated the antitrust laws turned on "whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments." Pet. App. 54a. In the Commission's view, that "question can be answered without an inquiry into the merits of the patent litigation." *Ibid.* The FTC reasoned:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry

> beyond the date that represents an otherwise reasonable litigation compromise.

Id. at 76a-77a (footnote omitted). Finding no proof of other offsetting consideration for the payments to either Upsher or ESI, the Commission found the agreements illegal. *Id.* at 87a-93a, 141a-145a.

3. The court of appeals set aside the FTC's decision and vacated its remedial order. Pet. App. 1a-35a. In the court's view, it was undisputed that the '743 patent gave Schering "the lawful right to exclude infringing products from the market until September 5, 2006," *i.e.*, the patent's expiration date. *Id.* at 20a. The court found it significant that Complaint Counsel "acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006," and that the absence of proof of an alternative entry date "reinforces the validity and strength of the patent." *Ibid.*

The court then turned to the question whether there was "substantial evidence to support the Commission's conclusion that the challenged agreements restricted competition beyond the exclusionary effects of the '743 patent." Pet. App. 20a. With respect to the Upsher agreement, the court noted that the "FTC concede[d] that its position fails if it cannot prove a direct causal link" between the $60 million payment and Upsher's delayed entry into the market. *Id.* at 21a. The court concluded that "the substantial and overwhelming evidence" supported the ALJ's conclusion that the $60 million payment to Upsher represented a bona-fide license payment for Upsher's products. *Id.* at 26a.

With respect to the ESI agreement, the court stated that "there is far less development of the factual record" to support the FTC's conclusion that the ESI settlement was unreasonable. Pet. App. 27a. Moreover, the court observed that the FTC had not rebu''ed the testimony of Schering's experts

"who posited that Schering would have won the patent case" and that the agreed entry date "reasonably reflected the strength of Schering's case." *Ibid.* The court accordingly found "the terms of the settlement to be within the patent's exclusionary power." *Id.* at 28a. The court attributed the FTC's contrary holding to the assumption "that but for the payments, the parties would have fashioned different settlements with different entry dates." *Id.* at 30a. The court found, however, that "no evidence in the record" supports the FTC's assumption that "the parties could have attained an earlier entry without the role of payments." *Ibid.*

The court concluded that antitrust liability should be determined by "the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection." Pet. App. 35a. The court observed that "[r]everse payments are a natural by-product of the Hatch-Waxman process," which weakened the relative bargaining power of a drug patent holder in settlement negotiations with an allegedly infringing generic manufacturer. *Id.* at 32a (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)). For instance, the court observed, "[d]ue to the 'asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'" *Id.* at 34a (quoting *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004)). As a result, "the mere presence of" a reverse payment could not provide "the sole basis for a violation of antitrust law." *Id.* at 34a, 35a. Rather, the court explained, there is also a "need to evaluate the strength of the patent." *Id.* at 35a.

DISCUSSION

The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market combined with a "reverse" payment from the patent holder to the alleged infringer. As the petition explains (at 15-21), such settlements may pose a risk of restricting competition in ways that are not justified by a lawful patent, to the detriment of consumers. This case, however, does not present an appropriate opportunity for this Court to determine the proper standards for distinguishing legitimate patent settlements, which further the important goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws.

I. The Petition Raises Important And Complex Issues

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the public interest. Settlements of patent infringement claims are often predicated on an agreement that the alleged infringer will not make and sell the allegedly infringing product in competition with the patentee and its licensees, or that it will do so only pursuant to the terms of a license agreement. Were it not for the existence of the patent and the allegation of infringement, a court would likely treat such an agreement as an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

In the patent context, however, a settlement involving restrictions on the sale of the products in question is not necessarily impermissible. The Patent Act provides that "[e]very patent shall contain * * * a grant * * * of the right to exclude others from making, using, offering for sale, or selling

the invention." 35 U.S.C. 154(a)(1). A valid patent thus confers on the patent holder the lawful "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Patent holders can lawfully refuse to license competitors to produce the patented article, or can grant exclusive territorial or other limited licenses to one or more chosen licensees. *Ibid.*; 35 U.S.C. 261, 271(d)(4); *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001).

At the same time, competitive restraints adopted as part of a patent litigation settlement are subject to invalidation under the antitrust laws if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford," *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason for concern about the competitive consequences of a settlement that includes substantial payments from the patent holder to the alleged infringer. Such payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market, and may result in less competition than would likely have prevailed in the absence of the payment. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719. 1749 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 408 (2003).

Reverse payments made in cases subject to the Hatch-Waxman Act may raise additional concerns when the brand name patent holder settles with the first generic competitor to file an ANDA. "It is widely understood that the 180-day exclusivity period," which is granted to the first ANDA filer and is not triggered until the first filer's entering the market or a finding of invalidity or non-infringement, creates an incentive for the parties to "settle the litigation with a 'non-en-

try' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Hovenkamp, 87 Minn. L. Rev. at 1755; see 21 U.S.C. 355(j)(5)(B)(iv). On the other hand, the Hatch-Waxman Act may also create unique justifications for reverse payments, because the ability of prospective generic competitors in effect to force patent holders to initiate infringement litigation upon the filing of ANDAs, before any actual infringement has occurred, reduces the litigation risk for the generic manufacturers. In combination with the inherent difficulties in predicting litigation outcomes and the potentially devastating consequences for the patent holder if it were to lose the litigation, the resulting gross disparities in the litigants' respective risks may tend to increase the cost of settlement for patentees in the Hatch-Waxman context and make reverse payments more likely, even when the patentee's legal claims are strong. See Pet. App. 31a; *In re Tamoxifen Citrate Antitrust Litig.* (*Tamoxifen*), 429 F.3d 370, 390-395 (2d Cir. 2005).

Patent litigation settlements that include reverse payments thus implicate conflicting policy considerations and complex legal issues at the intersection of patent and antitrust law, with further complexity introduced in the pharmaceutical context by the dynamics of the Hatch-Waxman Act. On the one hand, the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate patent holders' efforts to preserve weak patents by dividing their monopoly profits with settling challengers. The risks are magnified when the settling parties are in a position to utilize the Hatch-Waxman exclusivity period to further constrain competition from other generic manufacturers. On the other hand, the public policy favoring settlements, and the statutory right of patentees to exclude com-

petition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation. And the Hatch-Waxman context creates a litigation dynamic that makes some settlements reasonable.

Those competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed *ex ante*. Cf. States Amici Br. 18 (suggesting that an "appropriate analysis of an antitrust challenge of a patent infringement settlements * * * assesses the strength of the patent in the context of the infringement settlement itself").[1]

The FTC, however, apparently rejects any direct effort to evaluate the likelihood that the patent holder would prevail on its claim. Pet. App. 54a, 57a, 80a-87a, 143a; accord Pet. 16-19. The FTC apparently prefers to assess the "expected value" of the patent holder's lawsuit against the generic and then uses that as part of its evaluation of the settlement. Pet. 19 n.12; Pet. Reply 6. The FTC's petition emphasizes what it calls the the "'probabilistic' nature of the property interest created by the patent laws" and the view that "a patent is not a right to exclude, but rather a right to *try* to exclude." Pet. 16 (cita-

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[1] A court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner's litigation success. Rather, a court could conduct a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties' negotiations. Cf. *Weinberger* v. *Kendrick*, 698 F.2d 61, 74 (2d Cir. 1982) (Friendly, J.) (district court reviewing proposed class action settlement must form "an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated," but need not conduct a trial) (quoting *Protective Comm. for Indep. Stockholders of TMT Trailer Ferry, Inc.* v. *Anderson*, 390 U.S. 414, 424-425 (1968)), cert. denied, 464 U.S. 818 (1983).

tions omitted); cf. 35 U.S.C. 154(a)(1) (patent grants "right to exclude"), 282 (presumption of patent validity). In the end, the record below does not explore differences in outcome that might result from the FTC's emphasis on expected value and the apparently different emphasis of the court of appeals. On the other hand, the differences may not be substantial, as the expected value of the lawsuit should be a product of the relative strength of the competing claims. The FTC's approach, however, appears to place undue weight on the parties' subjective views of the strength of the claims as reflected in the settlement agreement, as opposed to a more objective assessment of the claims based on evidence extrinsic to the settlement. Likewise, the FTC's approach seems to reflect a high degree of suspicion of any reverse settlement payment. Under the FTC's view, the presence of a reverse payment (in the absence of an ancillary explanation for the payment, such as legal fees) has necessarily rendered consumers worse off and lessened competition, either because "a settlement with an earlier date might be compromised, *or* because continuation of the litigation without settlement would yield a greater prospect of competition." Pet. 19 & n.12. But cf. *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation), appeal dismisssed, 104 Fed. Appx. 178 (Fed. Cir. 2004).

II. This Case Does Not Provide A Good Vehicle For Addressing The Questions Presented

Whatever the correct standard for determining the antitrust treatment of patent settlements involving reverse payments, this case does not present an appropriate occasion to address that question or to assess the validity of the FTC's approach.

1. The court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed

market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's products. Pet. App. 21a-26a. After correctly articulating the well-settled principles of deference to agency fact-finding under the substantial-evidence standard of review (*id.* at 10a-12a), the court of appeals held that the evidence overwhelmingly supported the ALJ's conclusion that the payment was not linked to Upsher's delay in entering the market. *Id.* at 22a-26a. Unless overturned, that determination forecloses any antitrust challenge to the Upsher settlement, *even under the FTC's theory*.

The FTC asks this Court to determine whether "the court of appeals grossly misapplied" the substantial-evidence test by not deferring to the Commission's finding that the payment was for delay. Pet. I. There is, of course, no gainsaying the importance of appropriate deference to agency fact-finding. Nonetheless, plenary review of the court of appeals' application of the substantial-evidence standard in this case would not be an appropriate exercise of this Court's certiorari jurisdiction. Sup. Ct. R. 10. As the FTC recognizes (Pet. 26), "the task of determining whether substantial evidence supports agency findings is ordinarily left to the courts of appeals." Unless this Court departs from its normal practice, reviews the record, and determines for itself that substantial evidence supported the Commission's factual findings, there will be no occasion to consider the application of the antitrust laws to reverse payments with respect to the Upsher settlement.

The FTC argues that this Court "need not canvass the record itself and resolve the ultimate issue whether substantial evidence supported the Commission's findings, but may remand to the court of appeals for review of the factual issues under a proper standard." Pet. Reply 8. But the court of appeals set forth, and purported to apply, the "proper stan-

dard." Pet. App. 10a-12a. The FTC instead disagrees with the court's *application* of that well-established standard to the particular findings and record in this case. Accordingly, this case is not a candidate for a "correction" of the legal standard with a remand for the lower courts to apply the new standard.

Moreover, one of the principles of administrative law that was correctly articulated by the court of appeals is that a review for substantial evidence requires "a review of the record as a whole, which include[s] the ALJ's decision." Pet. App. 11a (citing *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 493 (1951)). Thus, this Court's resolution of whether the court properly deferred to the FTC would require review of not only the FTC's extensive findings, *id.* at 93a-141a, but also the ALJ's even more detailed findings, *id.* at 184a-249a, 316a-324a, which were made after a three-month trial that "covered 8,629 pages of transcript, involved forty-one witnesses, and included thousands of exhibits," *id.* at 8a, 22a. While there may well be valid grounds for taking issue with the court of appeals' application of the substantial-evidence standard to the Commission's careful findings, this Court generally does not sit as a court of errors to reexamine such determinations, and the complexity of this case renders it a poor candidate for an exception to that general practice.

2. Nor does Schering's $10 million payment to ESI provide an appropriate vehicle for resolution of the difficult and unsettled antitrust issues posed by the FTC. The Commission observed that "[a]s a matter of prosecutorial discretion, [it] might not have brought a stand-alone case based on [the] relatively limited evidence" involving the ESI agreement. Pet. App. 145a. Moreover, the payment was negotiated through a process involving the active participation of a magistrate judge, *id.* at 7a, who exerted "intense, and perhaps unseemly, judicial pressure to settle," *id.* at 144a. In finding

liability, the Commission stated that it wanted to "signal [its] disapproval of the way that Schering responded to judicial pressures," *id.* at 145a, but it did not suggest that such concerns are typical of reverse-payment settlements.

Finally, the $10 million reverse payment to ESI was conditioned on FDA approval of ESI's generic drug; "Schering doubted the likelihood of this contingency happening," and thus "if Schering's prediction proved true, it would not have to pay the $10 million." Pet. App. 7a. In short, the unusual circumstances surrounding the ESI payment suggest that it is unlikely to provide a factual setting conducive to the Court's identification and application of the appropriate legal standard to govern reverse-payment settlements generally. Cf. *id.* at 28a (noting that the FTC's invalidation of the ESI payment "would leave settlements, including those endorsed and facilitated by a federal court, with little confidence").

3. Further militating against review is the fact that the court of appeals did not squarely address the theory of antitrust liability advanced by the FTC in this Court. The court of appeals did not interpret the FTC's decision to be based on the notion that a patent holder may lawfully exclude infringing products only to the extent of the "expected value" of the patent holder's lawsuit against the generic. Pet. 19 n.12. The court instead understood the FTC's theory of liability to "require[] the conclusion that but for the payments, the parties would have fashioned different settlements with different," and earlier, entry dates. Pet. App. 30a; see *id.* at 17a n.15. And the court found "no evidence in the record" to support a conclusion that the parties could have, let alone would have, reached a more pro-competitive settlement in the absence of any reverse payments. *Id.* at 30a.

The FTC argues that the court of appeals misconstrued the Commission's rationale, for example, by attributing to the FTC a focus on the entry date of a hypothetical non-cash set-

tlement. But even the FTC concedes that such analysis played some role in its decision. Pet. 18; Pet. Reply 6. In any event, any disconnect between the court of appeals' understanding of the FTC's view and the FTC's own understanding of its rationale hardly counsels in favor of using this case as a vehicle for plenary review.[2]

Nor has any other court of appeals expressly considered the "expected value" analysis emphasized by the FTC. Indeed, only a district court thus far has examined, and rejected, the view that a patent gives the holder merely a potential right to exclude infringing competitors from the market. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (*Ciprofloxacin*), 363 F. Supp. 2d 514, 531-533 (E.D.N.Y. 2005), appeal docketed, No. 05-2851 (2d Cir. June 7, 2005). The Second Circuit may address the validity of that theory in its consideration of that case. That prospect further counsels against plenary review at this juncture.

III. There Is No Circuit Split Justifying This Court's Review

The FTC also argues (Pet. 23) that this Court's review is warranted to ensure national uniformity regarding the appropriate standard for assessing the validity of reverse payments. The FTC argues (Reply Br. 3 n.1) that the decision below is "at odds" with the Sixth Circuit's decision in *In re*

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[2] Portions of the FTC's decision suggest that the Commission was relying on the notion that an earlier settlement entry date was, in fact, achievable by the parties in the absence of a reverse payment. Pet. App. 51a ("The issue is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments."); *id.* at 82a ("we * * * focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement"); *ibid.* ("we * * * look * * * to determine whether * * * [the settlement] likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

Cardizem CD Antitrust Litigation, 332 F.3d 896 (2003), cert. denied, 543 U.S. 939 (2004), which held that an interim settlement agreement with a reverse payment constituted a per se violation of the antitrust laws. As the United States and the FTC previously informed this Court, however, the Sixth Circuit's decision involved payments to exclude drugs that did *not* fall within the scope of the patent alleged to be infringed, and thus it is far from clear that the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case. U.S. Amicus Br. at 11-15, *Andrx Pharmaceuticals, Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779).

The FTC also argues that the court of appeals' decision "has sharpened the tension between the Sixth and Eleventh Circuits," stating that the decision below, in conjunction with the Eleventh Circuit's previous decision in *Valley Drug*, *supra*, "effectively immunize" reverse payments from antitrust liability when the settlement is within the nominal outer bounds of the patent, absent proof that the patent litigation was a sham. Reply Br. 3; accord Pet. 14-15, 17, 19 n.12. But the decision below simply does not speak to the question, implicated in *Cardizem*, of the appropriate standard to govern a naked restraint of trade concerning drugs *not* covered by a patent, so it neither deepens nor sharpens the tensions, if any, between the approaches followed by the Sixth and Eleventh Circuits.

In any event, it is far from clear that the FTC is correct in construing the decision below as "complet[ing] the barrier against antitrust challenges to patent settlements." Reply Br. 3 n.1. The Eleventh Circuit in *Valley Drug* held that reverse payments were not subject to a per se rule, 344 F.3d at 1306, and rejected the imposition of antitrust liability "merely because" of a subsequent authoritative determination of patent invalidity, *id.* at 1308. Neither *Valley Drug* nor the decision below holds, however, that evidence of invalidity or non-in-

fringement available at the time of settlement would be irrelevant in assessing the permissibility of a reverse payment.

To be sure, the decision below notes that the FTC did not allege that the "infringement suits against Upsher and ESI were 'shams'" (Pet. App. 20a), but the court did not purport to hold that proof of "sham" litigation is a prerequisite to antitrust liability. Instead, the decision below states that the "proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 17a (citing *Valley Drug*, 344 F.3d at 1312). That holding does not expressly foreclose a party challenging a patent settlement from relying on an *ex ante* view of the strength of the infringement claim in determining whether the settlement, including any reverse payment, delayed entry beyond "the exclusionary potential of the patent." *Ibid.*

Because the FTC in this case eschewed any direct inquiry into the underlying merits of Schering's patent claims against Upsher or ESI, the court of appeals had no occasion to consider the appropriate nature or scope of such an inquiry. While the three-factor test articulated by the court of appeals does not expressly address the strength of the patent claim, portions of the court of appeals' decision suggest that the court approved of the ALJ's analysis, which assessed "the strength of the patent" in determining whether the reverse payment enabled Schering to achieve an anticompetitive outcome inconsistent with the patent's legitimate exclusionary reach. Pet. App. 9a, 15a; accord *id.* at 27a (observing that "Schering produced experts who posited that Schering would have won the patent case, and that the ESI's January 1, 2004, entry date reasonably reflected the strength of Schering's case."); *ibid.* (noting that "[t]he Commission * * * refused to consider the underlying patent litigation."). And in con-

cluding its opinion, the court of appeals again "underscore[d] the need to evaluate the strength of the patent." *Id.* at 35a. Accordingly, the decision below does not hold that a "sham litigation" standard should govern future antitrust challenges to reverse payment settlements.

After the FTC filed its reply brief in this Court, the Second Circuit decided *Tamoxifen*, 429 F.3d at 389, which held that reverse payments in patent settlement did not constitute a per se violation of the antitrust laws. That decision suggests that a sham standard governs the validity of settlements that do not exclude a patented product beyond the scope of the patent. *Id.* at 396-398 & n.27. Far from expressing any disagreement with the Eleventh Circuit's decision below, however, the Second Circuit explicitly approved of the Eleventh Circuit's focus on whether "the exclusionary effects of the agreement exceed the scope of the patent's protection," *id.* at 397 (internal quotation marks and citation omitted). In any event, to the extent that the Second Circuit's approach may differ from that followed below, review would not be warranted in this case, because the FTC's claims would fail under either approach. Moreover, the Second Circuit's decision did not involve drugs outside the patent claim and it thus does not create any split with the Sixth Circuit's *Cardizem* decision.

Finally, the above cases illustrate that the FTC is mistaken in suggesting (Pet. 24) that the Eleventh Circuit's decision forecloses further consideration of the issue by other courts of appeals. The FTC surmises (*ibid.*) that parties to patent settlement are likely to challenge any future action by the Commission in the Eleventh Circuit "without running the risk of a conflicting ruling from another circuit." But *private* parties (such as injured drug consumers) challenging reverse payments are just as likely to avoid bringing their claims in the Eleventh Circuit. Indeed, the challenges to reverse payments involved in the Sixth Circuit and Second Circuit deci-

sions were brought by private litigants. Moreover, the private party in *Ciprofloxacin*, 363 F. Supp. 2d at 531-533, challenged the patent settlement based on the FTC's theory of liability, and private parties and the State of Pennsylvania have brought suit in federal district court within the Third Circuit to challenge the very settlement agreements at issue in this case. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D. N.J. 2004). There is thus no basis for assuming that a conflict could not develop on the issue.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 05-273

IN THE
SUPREME COURT OF THE UNITED STATES

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF AARP AND THE PRESCRIPTION ACCESS LITIGATION PROJECT AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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MOTION OF AARP AND THE PRESCRIPTION ACCESS LITIGATION PROJECT FOR LEAVE TO FILE A BRIEF *AMICI CURIAE* IN SUPPORT OF PETITIONER

AARP is a nonprofit, nonpartisan membership organization of more than 35.8 million persons aged 50 and older, dedicated to addressing the needs and interests of older Americans. The Prescription Access Litigation Project (PAL) is a project of Community Catalyst, a nonprofit, nonpartisan organization that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all.

Pursuant to Supreme Court Rule 37(2)(b), AARP and PAL hereby move the Court for leave to file an *amici curiae* brief before the Court's consideration of a petition for a writ of certiorari. Counsel for Respondent, Schering-Plough, has withheld consent. Counsel for Petitioner, the FTC has consented.

INTEREST OF *AMICI CURIAE*

AARP works to ensure that everyone has access to needed health care and prescription drugs, but prescription drug treatments are particularly important to older persons who have the highest rate of prescription drug use. Persons over 65, although only 13 percent of the population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000).

Because prescription drug spending has skyrocketed over the last fifteen years, limiting AARP's members access to medically necessary medicines, AARP advocates for policies which can lower the cost of prescriptions for consumers. Since May of 2004, AARP's Public Policy Institute has issued a series of reports that closely monitor the pricing actions of the pharmaceutical industry. *See, e.g.*, David Gross et al., *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans – First Quarter 2005 Update*, AARP Public Policy Institute (July 2005), *available at* http://assets.aarp.org/rgcenter/health/dd122drugprices.pdf. Because generic drugs are generally much lower in cost, AARP has worked at the state and national levels to increase access to lower cost generic versions of drugs. AARP has filed *amicus curiae* briefs in prescription drug litigation related to access to generics in several cases, including *In re Cardizem CD*

Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert denied sub nom Andrx Pharma., Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004); *Valley Drug Co., v. Geneva Pharms., Inc.* 344 F.3d 1294 (11th Cir. 2003) *cert. denied sub nom Walgreen Co. v. Abbot Labs.*, No. 03-1178 (Oct. 12, 2004). AARP, interested in all aspects of access to pharmaceuticals, has also filed an *amicus curiae* brief in the recent case of *Merck KgaA v. Integra Lifesciences I, Ltd.*, _U.S._, 125 S. Ct. 2372 (2005)(involving patent infringement exception in Hatch-Waxman Amendments), and is recommending the Court grant *certiorari* in *Teva v. Pfizer*, No. 05-48 (whether declaratory judgment jurisdiction exists over generic's challenge of patent.)

PAL is a coalition of over 110 organizations in 35 states and the District of Columbia. The organizations in PAL's coalition have a combined membership of over 13 million people, and include state and local organizations representing consumers and seniors, statewide health care access coalitions, and labor unions. PAL works to end illegal prescription drug price inflation by pharmaceutical manufacturers and others by facilitating the participation of consumers and consumer organizations in class action litigation challenging such price inflation practices.

Three organizations that are members of PAL's coalition are plaintiffs in the *In re K-Dur Antitrust Litigation* case (D.N.J. Case No. 01-1652, MDL No. 1419): New York Statewide Senior Action Council, Massachusetts Senior Action Council, and the Consumers for Affordable Healthcare

Coalition.[1] Organizations in the PAL coalition are involved in a number of other antitrust cases concerning generic drugs. PAL sees the availability of generic drugs as key to ensuring that prescription drugs are affordable and subject to competition. PAL is concerned that a variety of tactics by brand name pharmaceutical manufactures, including the filing of unwarranted patents, frivolous patent infringement litigation and settlement agreements not to produce a generic version of a drug, are harming competition, impinging on the public's access to affordable generic drugs and undermining Congress's intent in passing the Hatch-Waxman Act.

AARP and PAL have a great interest in the question of whether settlement agreements between prescription drug manufacturers blocking the entry of generics to the market violate the anti-trust laws. It is in all consumers' interest to assure that generic alternatives to brand name drugs will be available as soon as possible. Agreements that serve to delay lower cost generics' entry in the marketplace harm the consumers which *amici* represent.

AMICI'S BRIEF IS RELEVANT AND NONDUPLICATIVE

The Court of Appeals concluded its opinion noting that its reversal of the FTC enforcement decision was based on policy considerations. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1076 (11th Cir. 2005). However, the only policy benefit it achieved in ruling as it did was to encourage

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[1] AARP Foundation Litigation (AFL) is part of the AARP Foundation, a 501(c)(3) organization affiliated with AARP. AFL attorneys, along with several other law firms who are lead counsel in the K-Dur MDL, have also been co-counsel for these plaintiffs in that case.

settlement of litigation. The Court of Appeals ignored the countervailing policy considerations such as the harm caused to individuals by the high costs of drugs due to monopolization, and disregarded the expressed Congressional policy of promoting the swift entry of generics into the market by encouraging generic manufacturers to challenge weak patents. *Amici* respectfully submit that in highlighting the other policy goals which were glossed over by the Eleventh Circuit and the parties, they can bring the attention of the Court to a perspective not otherwise presented within the parties' legal arguments. *Amici* have considerable experience representing pharmaceutical consumers interests in a variety of forums, and would like to offer this information to help give context to this Court's decision whether to grant certiorari.

CONCLUSION

For the forgoing reasons, *amici* AARP and PAL respectfully request that leave to file their brief be granted.

September 30, 2005

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No. 05-273

IN THE
SUPREME COURT OF THE UNITED STATES

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF AARP AND THE PRESCRIPTION ACCESS LITIGATION PROJECT AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE*[1]

The statements of interest are contained within the forgoing motion for leave to file this brief.

[1] Pursuant to Supreme Court Rule 37.6, no counsel for any party authored any portion of this brief. No persons other than *amici curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief.

SUMMARY OF ARGUMENT

The Eleventh Circuit expressly rested its decision on policy grounds but considered only the value of settlement of litigation, ignoring countervailing policies. Settlements of patent litigation, featuring reverse payments which delay entry of less expensive generic versions of drugs to market, frustrate Congressional attempts to allow generic entry when patents should not rightfully exclude competition. In the 1984 Hatch-Waxman Amendments, and now nearly 20 years later in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress has declared its policy to speed generic versions of drugs to market. Congress has acted because the high costs of prescription drugs are threatening consumers' health. Research shows that consumers react to higher prices by reducing consumption of drugs, but many will choose to switch to lower cost generic versions of drugs if they are available. The greatest price reductions result not from competition between a brand name and generic drug maker but from competition between generic drug makers as more of them enter the market. The Court should grant certiorari to determine if settlements of prescription drug patent disputes are beyond antitrust liability.

REASONS FOR GRANTING THE PETITION

A. Introduction.

While settlement of disputes may be a worthy policy goal, the Eleventh Circuit offers no reason why encouragement of prescription drug patent settlements should trump the countervailing considerations of fair market competition and consumer access to affordable medication. This Court should grant review because it should decide the important federal question the Eleventh Circuit identified, determining exactly

what is "the confluence of patent and antitrust law." *Schering-Plough v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005). However, this Court should properly balance all the policy goals which Congress has sought to achieve, including those of competition and increasing consumers' access to lower cost prescription drugs.

B. Reverse Payments with Delay of Competition Patent Settlements May Be Win-Win for Drug Manufacturers But Are Lose-Lose For Competition and Consumers.

Schering, Upsher and AHP are not the only companies which have entered into settlements featuring reverse payments, in which, rather than resolving the patent dispute to determine whether the name brand manufacturer should have the ability to continue to exclude competition, the parties create a limbo where only consumers suffer harmful consequences. The name brand manufacturer wins because its patent remains unchallenged, and the generic manufacturer gets paid to not produce anything. The latter payments are known as reverse payments for two reasons. First, moneys paid in settlement normally flows to the injured party. Here, the alleged infringer gets the money, normally quite a handsome sum. Second, in patent disputes, where the patent's exclusion of competition is valid, payment normally flows to the pioneer in exchange for either infringement damages or a manufacturer's license. But in these settlements, money flows in the reverse direction, to the generic.

The FTC's 2002 study of whether settlements of prescription drug manufacturers' patent litigation often resulted in the practice of reverse payments found this perverse result surprisingly common. In that study, nine of twenty final patent litigation settlements contained provisions providing that the

brand-name manufacturer make a payment to the generic manufacturer. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 17 (2002). Each of these agreements prohibited marketing of the generic until the patent expired or, in two cases, until an agreed-upon date. *Id.* at 31. The reverse payments ranged from $1.75 million to $132.5 million, and the delay of generic entry was from four months to ten years. *Id.*

C. Patent Settlement Agreements Amongst Manufacturers Which Delay Entry of Competition Pervert Congress' Intent to Speed Generic Entry.

1. Congress Intended To Benefit Consumers By Getting Generics to Market.

Twenty years ago Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act). Pub. L. No. 98-417, 98 Stat. 1585, *codified at* 35 U.S.C. § 271(e)(1) (2005). One of the major purposes of the legislation was "to make available more low cost generic drugs." H.R. Rep. No. 98-417, pt. 1, 2648-50 *reprinted in* 1984 U.S.C.C.A.N. 2647 (1984). Congress specifically noted its intent that "[o]lder Americans, in particular, would benefit" from the law because of their great need for affordable prescription drugs. *Id.* Government programs which paid for prescription drug coverage would also have substantial savings because of the availability of generic drugs. *Id.* at 2650.

Hatch-Waxman rewarded innovation by preserving patent holders' rights compromised by the time it took to secure

regulatory approval for the marketing of their medications, and, at the same time, created a regulatory process intended to prevent a *de facto* patent extension equal to the time it would take a competitor to comply with the regulatory requirements required to bring a drug or medical device to market. *See* H.R. Conf. Rep. No. 98-417, 2647-2648 (stating that a purpose of the bill is to make more generic drugs available and to increase incentives for new research and development). Hatch-Waxman intended to balance the rights of patent holders with the competing priority of speeding generic drugs to market.[2]

In order to create that balance, Congress altered the traditional relationship between pioneer and generic drug makers, including the assumed inviolability of patents, in order to speed generics to market. Hatch-Waxman did several things to weaken the monopoly powers granted to patented drug products. As this Court recently recognized in *Merck KgaA v. Integra Lifesciences I., Ltd.*, __ U.S. __, 125 S.Ct. 2372 *(2005)*, Congress created a statutory patent exception allowing the free use of patented items to perform experiments related to regulatory approval of health care products, prior to the expiration of the patent term. 35 U.S.C.§ 271(e)(1); *see also, Eli Lilly v. Medtronic*, 496 U.S. 661 (1990)(exception applies to medical devices).

Hatch-Waxman also created a mechanism to allow generic manufacturers to invent around and dispute a patent and then challenge that patent in court before bringing the generic to market. Congress established the abbreviated new drug application (ANDA), a shorter approval process for generic versions of drugs already on the market. 21 U.S.C.

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[2] *See* 97 Cong. Rec. 24,434 (1984) (statement of Cong. Waxman) (explaining that Congress "tried to balance . . . interests. That was the whole course of the negotiations on this legislation").

§ 355(j)(2)(a). The Act provides that the filing of an ANDA creates a constructive act of patent infringement. The generic can test the strength of the patent before the brand name incurs damage by the generic marketing its product, and the generic risks being liable to the brand for millions of dollars. 21 U.S.C. § 355(j)(5)(B) and (C). The first generic to file an ANDA which successfully demonstrates that it does not violate a patent is given a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (1984), *amended by* 117 Stat. 2066, Pub. L. 108-173 § 1102 (2003). Congress intended this 180-day period to provide "a reward for challenging monopolists' abuse of weak patents[,]" and for bringing costly patent litigation against the patent-holder. James T. O'Reilly, *Prescription Pricing and Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. Ky. L. Rev. 413, 414 (2002).

Congress intended for courts to determine whether patents were sufficient to exclude competition. But these reverse payment settlement agreements which delay generic competition, not only block courts from rendering a decision as to the scope of the patent, but also deprive consumers of the very benefit the law sought to obtain: increased competition. Congressional purpose will be frustrated if the courts see these settlements as a natural by-product of Hatch-Waxman, rather than examine them for anti-competitive consequences to consumers. [3] The problem with settlements with reverse

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[3] *Compare In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 262 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (finding that reverse payments are a natural by-product of the Hatch-Waxman Act, "even if such payments were not contemplated or intended") *with* FTC Opinion at 28 (rejecting argument that reverse payments are a natural by-product of Hatch-Waxman based on Congressional intent).

payments is that they satisfy only one of the aspirations of Hatch-Waxman—the protection of the patent-holder, but do so by sacrificing the other aspiration of making generic drugs available sooner. Representative Waxman commented on this perversion, saying, "'The law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened.'"[4] The Act was intended to benefit consumers, not to allow a different allocation of the total profits on a drug between horizontal market participants.[5] Because these agreements block increased competition, the FTC is right to question them as unreasonable restraints on trade.[6]

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[4] Sheryl Gay Stolberg and Jeff Gerth, *Medicine Merchants Holding Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. Times, July 22, 2000, *available at* www.dimenet.com/dpolicy/cgi/getlink.cgi?344 (quoting Cong. Waxman).

[5] *See* 97 Cong. Rec. 24,427 (1984) (statement of Cong. Waxman) (elaborating on the intent behind the Hatch-Waxman Act by observing that "at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of this legislation").

[6] The Eleventh Circuit's categorization and rejection of the FTC's rule of law in this case as "automatically invalidating any agreement" with reverse payment and delay of generic entry seems utterly misplaced. *Schering*, at 1076. After a trial and appeal using the rule of reason analysis, this examination by the FTC of these companies' behavior can not appropriately be called an automatic invalidation.

2. Policy-Makers and Courts Must Monitor Manufacturers Who Game the System.

Congress has recognized that abusive practices of pioneer drug companies and potential generic competitors have stalled the arrival of generics on the market.[7] They are aware these tactics delay consumers' access to affordable medications. As a result, Congress recently amended the law and passed Title XI - "Access to Affordable Pharmaceuticals" of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 117 Stat. 2066, Pub. L. 108-173 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.). Congress limited the stay of generic competition granted to name brand manufacturers following instigation of litigation when generic manufacturers filed ANDAs to a single 30 month period, thereby "allowing lower-priced generic products to enter the market more quickly." Joint Explanatory Text to the MMA Conference Agreement, H.R. Conf. Rep. No. 108-391, at 836 (2003) *reprinted in* 2004 U.S.C.C.A.N. 2187. This prohibited the practice of name brand manufacturers from stacking patents to block competition for successive 30 month periods. Congress also restructured the 180-day exclusivity period to prevent "parking" of the exclusivity period through

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[7] *See* Testimony of Timothy J. Muris, Chairman Federal Trade Commission, before the United States Senate Committee on the Judiciary, *The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace* (June 17, 2003) (presenting the findings of its report, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002)); David Gross, AARP Public Policy Institute, *Generic Drugs*, AARP Issue Brief at 15 (2003), *available at* http://research.aarp.org/health/ib61_generic.html.

pioneer-generic agreements not to market the generic, thereby delaying other generics indefinitely.

The law now provides that exclusivity is forfeited if the generic does not come to market within a set amount of time. 21 U.S.C. § 355 (j)(5)(D)(2005). Congress also required that notice of settlements like the ones in this case be filed with the government's antitrust agencies. *See* MMA, §§ 1111-1118 (codified at 21 U.S.C. § 355 (notes)). But unless the courts enforce the antitrust laws against parties whose settlement agreements delay or halt competition, the companies will continue to find ways to game the system benefitting themselves to the detriment of consumers.

D. Delaying Entry of Lower-Priced Generic Prescription Drugs Harms Consumers.

1. High Prescription Drug Costs Threaten Older Consumers' Health.

U.S. spending for prescription drugs has quadrupled since 1990, leaping from $40.3 billion to $179.2 billion in 2003.[8] Although prescription drug spending constitutes 11% of the total health care spending for the general population, it is one of the fastest growing components, increasing at double digit rates each of the last seven years. Kaiser Family Foundation, *Prescription Drug Trends* (Fact Sheet) 1 (May 2003), *available at* www.kff.org/rxdrugs/3057-03-index.cfm. Spending for prescription drugs grew by 10.7.% from 2002 to

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[8] Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Percentage Change, by Type of Expenditure: Select Calendar Years 1980-2003 *at* www.cms.hhs.gov/statistics/nhe/historical/t2.asp.

2003, and outpaced growth in all other health care services.[9] Increased demand by an aging population, as well as new, more expensive drug therapies becoming available have contributed to rising drug spending. However, increased drug prices are a substantial contributor to the increase in our nation's expenditure on drugs. The increase in prices constitutes a quarter to one-third of the rise in drug spending. *See, e.g.*, David Kreling et al., *Prescription Drug Chartbook: An Update* 40 (Kaiser Family Foundation, 2001); Stanley S. Wallack et al., *Recent Trends in Prescription Drug Spending for Insured Individuals Under 65 and Age 65 and Older* (Schneider Institute for Health Policy, Brandeis University, 2001).

For older Americans, prescriptions account for 19% of the average total out-of-pocket spending on health care (not including home care and long-term nursing home costs). Prescription drugs comprise the largest category of their health care expenses after premium payments.[10] From 2000 to 2003, the average annual growth rate in manufacturers' prices of brand name drugs most used by older persons was 6%. David Gross, Stephen Schondelmayer, Susan Kaetzman, *Trends in Manufacturers Prices of Brand Name Prescription Drugs Used by Older Americans 2000 Through 2003*, #2004-06 AARP

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[9] *Id.*

[10] Normandy Brangan & Mary Jo Gibson, *FYI: The Cost of Prescription Drugs: Who Needs Help?*, AARP Public Policy Institute (Oct. 2000), *available at* http://research.aarp.org/health/fyi_cost .html. By 2014, prescription drug spending is expected to be $521.3 billion. Centers for Medicare & Medicaid Services, National Health Expenditures Amounts and Average Percentage Change by Type of Expenditure: Select Calendar Years 1998-2014 *at* www.cms.hhs.gov/statistics/nhe/projections-2004/proj 2004.pdf.

Public Policy Institute vi (May 2004 revised June 2004), *available at* http://research.aarp.org/health/2004_06_drugprices.pdf. This increase is much larger than the increase in inflation, and the gap between rising prescription drug prices and the general rate of inflation has been widening. On average, the manufacturer prices for widely used brand name prescription drugs rose 4.1% in 2000 and accelerated to 6.9% in 2002, while the annual rate of general inflation actually fell from 3.4% in 2000 to 2.3% in 2003. *Id.*

Research and surveys show that uninsured, older and chronically ill people go without drugs when costs become too great a factor. Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension,* 19 Health Aff. 219, 228 (2000). This study of drug coverage analyzed the relationship between cost and purchases from a national sample of people 65 and older, finding that a "one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year." *Id.* There is "specific, empirical evidence that financial barriers compel older Americans to forgo needed drug treatment." *Id.* A more recent survey confirmed those findings. Dana Gelb Safran, et al., *Prescription Drug Coverage and Seniors: Findings From A 2003 Survey* Health Aff. (Web Exclusive) 157-58 (Apr. 19, 2004) (12.8% of all adults report not getting prescription drugs because of cost.) A national survey of Americans aged 45 or older reported that more than one in five (22%) did not fill at least one prescription prescribed by their doctor. AARP, *Prescription Drug Use Among Persons Age 45+: A Chart Book June 2002,* 24 (2002), *available at* http://research.aarp.org/il/rx_charts.pdf. The cost of the drug was the main reason people cited for not getting their prescription filled. *Id.* at 25. Of particular concern is the fact that cost deters a growing proportion of the population from

taking medically necessary medicines, up from 13% during a 1986 survey to 22% in 2002. *Id.* at 72.

Without doubt, increasing access to lower-cost generic drugs is one way to assure that consumers will fill the prescriptions they are given and take the dosages they need. Each patent settlement agreement that results in generic competition being stifled or delayed means that individual consumers are going without because they cannot afford the monopolist's prices.

2. Generic Drugs Reduce Medication Costs and Consumers Quickly Substitute Generic Drugs, Causing a Decline in the Market Share of Brand Name Drugs As More Generics Enter the Market.

Because generic drugs are priced much lower than their brand name counterparts, they are a source of substantial savings. In 2003, the Food and Drug Administration reported that the average price of a brand name drug is $72 while the average price of its generic version is $17, or less than a quarter of the brand's price.[11]

Most of the reduction in total spending for a branded drug is caused by substitution of generic prescriptions for brand

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[11] U.S. Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html.

prescriptions.[12] Since consumers are likely to substitute a generic for a brand name, the name brand manufacturer has a strong incentive to limit the number of generic competitors in an effort to keep a greater market share.

The sooner more companies offer the same generic product, the greater the price competition and the lower price consumers pay for a generic version of a drug product.[13] At the time of market entry, the generic price is about 60% of the branded counterpart's price; within the first two years on the market, the generic price will decline by an average of 35%. Grabowski, *supra*, at n.13. As a result, after two years, the generic drug price falls to about one-third of the branded counterpart's price.

Highly successful blockbuster drugs face steeper declines in market share after generic entry than less successful

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[12] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* ch. 3 (July 1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence =0. (hereinafter CBO); Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PharmacoEconomics 110, 115 (1996) (hereinafter Grabowski); Michie I. Hunt, BlueCross BlueShield Association, *Prescription Drug Costs: Federal Regulation of the Industry* 61 (2000).

[13] Bureau of Competition & Policy Planning, Federal Trade Commission, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications* 4-5 (Nov. 4, 1999) *available at* http://www.ftc.gov/be/v990016.htm; CBO, *supra* at ch. 3; Grabowski, *supra*, at 115; *see also In re Cardizem CD*, 332 F.3d 896 (6th Cir. 2003), *cert denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004).

branded products. Schering-Plough's successful K-Dur product faced a very steep decline when competition began – they lost $200 million in sales in one year. Schering reported K-Dur sales of $216 million in 2001, but in 2002, sales plunged to $16 million because of generic competition.[14] Today consumers can purchase 100 tablets K-Dur 20 for $62.23, or purchase the generic version Klor-Con M20 for $43.99.[15]

An agreement between Schering-Plough and its would-be competitors in 1997 which stalled competition until 2001 in the case of Upsher-Smith, and until 2004 in the case of ESI-Lederle, meant that millions of dollars of profits were maintained for the manufacturers, at the expense of consumers. Therefore, in situations like the one before the Court, where multiple generic competitors prepared to enter the market, but delayed entry after being paid not to enter the market, consumers are unjustly denied the lower price that generics would bring to the market. *See generally*, David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics* 4 (2002) ("generic drug prices fall with the number of competitors.")

Perhaps Schering could have prevented the competition if it had prevailed in the patent litigation, but through business arrangements with its competitors, it managed to insulate the only means of testing that patent to determine whether it could maintain a legal monopoly. Finding these actions inconsistent

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[14] Schering Plough Press Release, Schering-Plough Reports Sales, Earnings for 2002 Fourth Quarter and Full Year, Jan 23, 2003, *available at* http://www.schering-plough.com/schering_plough /news/release.jsp?releaseID=373944 last visited Sept.27, 2005.

[15] *See* drugstore.com, at http://www.drugstore.com/pharmacy/ prices/drugprice.asp?ndc=00085078701&trx=1Z5006 last visited Sept.28, 2005.

with Congressional intent, and resulting in harm to consumers, the federal agency responsible for enforcing our federal competition laws found the facts compelling enough to bring it to trial and decided that the agreements were an unreasonable restraint of trade. The Eleventh Circuit said that in evaluating the antitrust implications of a patent dispute, the analysis must "evaluate the strength of the patent." *Schering* at 1076. But the Eleventh Circuit did not examine the validity of the patent or whether the generic drugs did in fact infringe, but instead, presumed the patent was valid. *Schering*, at 1068. Based upon this, it concluded that the "exclusionary effects of the agreement" fell "within the protections of the '743 patent, and were therefore not illegal." *Schering*, at 1076. Discounting the Commission's evidentiary conclusions, the Eleventh Circuit substituted its judgment for whether or not the agreements were anti-competitive because it presumed the patent absolved the parties of antitrust liability.

V. CONCLUSION

The amount of competition between drug manufacturers directly impacts the costs people pay for medications, and the cost of medication has a direct correlation with whether or not people can afford to purchase and get the benefit of these drugs. Any delay in the availability of generic prescription drugs means that consumers' access to life-saving and health enhancing medications is being diminished. *Amici* believe the Eleventh Circuit's decision was flawed because it did not give sufficient weight to Congressional policy in Hatch-Waxman promoting generic competition even in the face of a patent.

For the foregoing reasons, this Court should grant certiorari and review the Eleventh Circuit's decision in this case to determine whether these agreements violated antitrust law.

September 30, 2005

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IN THE

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FEDERAL TRADE COMMISSION,

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Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Eleventh Circuit

MOTION TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF BAYER CORPORATION AS *AMICUS CURIAE* IN OPPOSITION TO CERTIORARI

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MOTION TO FILE *AMICUS CURIAE* BRIEF OF BAYER CORPORATION IN OPPOSITION TO CERTIORARI

Bayer Corporation ("Bayer") respectfully moves for leave to file the attached amicus curiae brief, pursuant to Supreme Court Rule 37.2(b), in opposition to certiorari.

Bayer is a research and science driven company that is engaged in the research and manufacture of several different kinds of products, including pharmaceutical products.

The questions presented in the Petition significantly affect Bayer Corporation because it manufactures a variety of patented products including patented drugs, is involved in litigation with respect to those products, and has entered and may enter in the future into settlements of such litigation. Bayer Corporation is a co-defendant in an antitrust case arising from the settlement of patent litigation in which the district court recently granted summary judgment for defendants. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005), *appeal filed*, No. 05-2851 (2d Cir.).

In accordance with Supreme Court Rule 37.2, Bayer represents that it obtained written consent from counsel for the petitioner to file amicus brief. Counsel for respondents Schering-Plough Corporation and Upsher-Smith Corporation declined to consent, however, thereby necessitating this motion. Sup. Ct. R. 37.2(b).

For these reasons and those set out in the accompanying brief, Bayer hereby moves the Court to allow it to appear as *Amicus Curiae*, and to submit its brief urging the Court to deny the petition for certiorari.

Respectfully submitted,

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STATEMENT OF INTEREST

The Statement of Interest of Bayer Corporation is included in the Motion to File.[1]

SUMMARY OF ARGUMENT

1. There is no circuit split or significant conflict as to the first question presented that warrants this Court's review. To the contrary, there now exists a significant body of uniform but still developing law holding both (i) that antitrust analysis of a pharmaceutical patent settlement must begin with an examination of the exclusionary effect of the patent and whether the settlement agreement exceeds that effect, and (ii) that payments from a patent holder to a potential infringer or challenger are not presumptively anticompetitive. The Petition fails to identify or address this growing body of case law, which contravenes the Commission's position here. Moreover, the Commission itself recently and correctly argued to this Court that there is no conflict in the circuits as to these issues.

2. Review is also unwarranted because the Petition asserts a theory of antitrust liability that was not the basis for the Commission's decision below and that has not been accepted by any circuit. The Commission's decision was based on the theory that the actual settlement chosen by the parties was unlawful because it prevented them from entering into a different settlement "better" for consumers. That position was rejected because it is contrary to the well-established rule that conduct does not run afoul of the antitrust laws solely because different conduct might yield greater competition.

The Petition now advances a different rationale, based on the proposition that patents confer only "probabilistic"

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than the *amicus* and counsel provided financial support for this brief.

rights, and that consumers have a property right in the possibility that a patent will be found invalid or not infringed. The Petition now contends that the settlement was therefore unlawful because it eliminated this "prospect" of competition. This new rationale does not merit review by this Court because it was not the basis of the Commission's decision and has not been accepted by any circuit. Because this theory would largely negate the value of patent rights and strongly deter most settlements of patent litigation, it should not be presented to this Court until further developed by the courts of appeals.

ARGUMENT

I. REVIEW OF THE EXCEPTIONALLY BROAD QUESTION PRESENTED IS NOT WARRANTED IN LIGHT OF THE ONGOING DEVELOPMENT OF THE LAW AND THE LACK OF ANY SPLIT IN THE CIRCUITS

The Petition primarily raises the broad question "[w]hether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade." Pet. I. In mounting its attack on so-called "reverse payments" in patent settlements, the Petition criticizes as "startling" the conclusion of the court below that the antitrust analysis of a patent settlement must begin by examining the "exclusionary potential" of the patent and whether the agreements at issue had exceeded that potential. *Id.* at 11. Neither the Commission's surprise nor review of this question are warranted.

A. The Petition Ignores The Uniform Body Of Law Contrary To The Commission's Position Here

The Petition fails to acknowledge, much less to address, the significant and uniform body of law contrary to the two fundamental premises of the Commission's argument.

First, the courts have repeatedly held that antitrust analysis of a settlement agreement between a patent holder and a potential infringer must begin with an examination of the exclusionary effect of the patent and whether the agreement exceeded that effect. In reaching the same conclusion, Pet. App. 17a, the court below followed its prior ruling in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004), that, "[w]hen the exclusionary power of a patent is implicated . . . the antitrust analysis cannot ignore the scope of the patent exclusion." *Id.* at 1310. Thus, only those provisions of the agreements "found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis." *Id.* at 1312.

This exclusionary effect analysis is wholly consistent with prior holdings by District of Columbia, Federal, Second, and Seventh Circuits.[2] Similarly, Judge Richard Posner, sitting as a district court judge, recently explained that conduct within the exclusionary effect of a patent could give rise to antitrust liability only where it is objectively baseless to assert that the patent is valid and infringed:

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[2] *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal. . . . None of these restraints go beyond what the patent itself authorizes."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("The appropriate criterion is whether Mallinckrodt's restriction . . . has ventured beyond the patent grant. . . . Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in grant of the patent").

> A firm that has received a patent from the patent office . . . and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Asahi Glass Co. Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003). Other District Courts agree that the exclusionary effect of the patent is the central inquiry of any antitrust analysis.[3]

Second, the courts have also consistently held that settlement payments from a patent holder to a potential generic manufacturer are *not* presumptively anticompetitive. Pet. App. 35a. The court below explained:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a

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[3] *See, e.g., Ciprofloxacin*, 363 F. Supp. 2d at 523 ("The ultimate question — and this is the crux of the matter — is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent."); *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326, 331 (E.D.N.Y. 2002), *appeal pending*, No. 03-7641 (2d Cir.) (refusing to remand a suit challenging a Hatch-Waxman settlement because "plaintiffs cannot succeed on their claims without proving the invalidity or unenforceability of Zeneca's patent"). *But see In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004). There, the court addressed the very same settlement by Schering-Plough that is the subject of the Petition here. In denying a motion to dismiss, the court followed the Commission's ruling that was reversed by the Eleventh Circuit in this case.

> potential infringer a substantial sum in settlement. . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Id. at 34a-35a (internal citations omitted). That conclusion was fully consistent with its prior decision in *Valley Drug*, where the court explained that "[i]f Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the [alleged] exclusionary effect . . . ." 344 F.3d at 1309.

Moreover, the Eleventh Circuit's rulings on this point are entirely consistent with numerous other recent decisions. As Judge Posner also explained:

> "Reverse payment" patent settlements . . . are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.

Asahi Glass, 289 F. Supp. 2d at 994 (citations omitted); *see also Ciprofloxacin*, 363 F. Supp. 2d at 540 ("The test for determining the validity of the so-called reverse or exclusion or exit payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims."); *Tamoxifen*, 222 F. Supp. 2d at 331-32 (rejecting plaintiffs' argument that "the Settlement

Agreement was anticompetitive based on the amount of money Zeneca paid to Barr").[4]

As these decisions reflect, the law affecting the broad question presented is developing in a steady, and generally uniform, manner. Further decisions are pending. The Second Circuit is currently considering the appeal from the District Court decision in *Tamoxifen*, which has been argued and submitted for over a year. *See supra* note 3. The Second Circuit also has before it the appeal from the ruling in *Ciprofloxacin*. *See* p. i *supra*. In both cases, there are motions pending to transfer some or all of the appeals to the Federal Circuit. Additional district court cases challenging Hatch-Waxman settlements are pending in the Third and Ninth Circuits. *See K-Dur*, 338 F. Supp. 2d 517; *Kaiser Found. v. Abbott Labs.*, No. 2:02cv2443 (C.D. Cal. filed March 22, 2002). Given these ongoing developments, review by this Court of the Petition's initial question is inappropriate.

B. The Commission Has Recently And Correctly Argued To This Court That There Is No Circuit Split On The Primary Question Presented

This Court "normally grant[s] only petitions that present an important question of law on which the lower courts are in conflict." *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S.

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[4] For further criticism of the view that so-called reverse payment settlements are presumptively anticompetitive, *see, e.g.*, Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 704 (2004); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements With Payments From Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777 (2003); Richard J. Gilbert & Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 78 (2001); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. Rev. 1789, 1802 (2003).

374, 408 (1995) (O'Connor, J., dissenting on the merits); *see also Lawson v. Murray*, 515 U.S. 1110, 1116 (1995) (Scalia, J., concurring in the denial of certiorari, where there was no "clear conflict with the decisions of other courts"). Here, the sole case that the Petition identifies as possibly in conflict with the caselaw described in Part I.A., *supra*, is *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms. Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004) (No. 03-779) ("*Cardizem*"). Pet. 23.

The Petition asserts that the Sixth Circuit in *Cardizem* has taken a "strikingly different approach" than has the Eleventh Circuit and describes *Cardizem* as "ruling that it may be per se unlawful for a patent holder to 'bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor . . . to stay out of the market.'" Pet. 23. Yet that description of *Cardizem* is "strikingly different" from the description of that case previously advanced by the FTC *to this Court* in *Cardizem* itself.

When the parties in *Cardizem* sought certiorari, this Court asked for the views of the United States. In response, the FTC joined the Solicitor General in an amicus brief explaining to the Court that *Cardizem* and the Eleventh Circuit's decision in *Valley Drug* "*do not present a square conflict* that necessitates this Court's review at this time." Brief for the United States as *Amicus Curiae* at 11, *Andrx*, No. 03-779 (U.S.) ("Br.") (emphasis added). The FTC told the Court that the Sixth Circuit had held a reverse payment settlement *per se* anticompetitive only where the "district court construed the Agreement at issue . . . to cover petitioner's marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation." Br. 7. Indeed, in its *amicus curiae* brief, the FTC emphasized two key facts of *Cardizem*: that the Agreement covered non-infringing competition and that it created a

bottleneck – a barrier to the entry of future generic challengers. Br. 13.[5]

Nor did the FTC stop there. It also told the Court that, if *Cardizem* were construed to "require a per se rule" for "every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product," "the court of appeals decision would be *erroneous*." Br. 12 (emphasis added). The *Cardizem amicus* brief explained that "[r]everse payment settlements may have the salutary effect of facilitating efficient settlements that advance consumer welfare," and that "[c]ertain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate." Br. 9, 12.

Having received these views of the United States, this Court denied certiorari in *Cardizem* and shortly thereafter denied certiorari in *Valley Drug*. *See* 125 S. Ct. 308 (2004) (No. 03-1175). It would thus be highly unusual for this Court to grant certiorari where the Court has recently denied certiorari on the same legal issue, and the petition fails to demonstrate a sharp conflict among the Circuits. As then-Justice Rehnquist once explained, absent a "square conflict," the Court's recent denial of certiorari in cases raising similar issues renders a grant of certiorari "doubtful":

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[5] The *Cardizem amicus* brief also pointed out that, in the very sentence in *Cardizem* on which the Petition now relies for a *per se* rule, the Sixth Circuit cited with approval Judge Trager's decision, 332 F.3d at 908 n.13 (citing *Ciprofloxacin*, 261 F. Supp. at 242), which had rejected the *per se* rule for a settlement within the exclusionary effect of the patent. Based on this, the government's amicus brief said that *Cardizem* should be read "as limited to the particular agreement before the court, which had been construed by the district court to restrain petitioner from marketing *non-infringing* or *potentially non-infringing* versions of *Cardizem* CD." Br. 12-13 (emphasis added).

> Twice within the last year this Court has declined to review similar Fourth Amendment claims in strikingly similar cases. . . . [U]nless applicants can demonstrate a conflict among the Courts of Appeals of which this Court was unaware at the time of the previous denials of certiorari, or which has developed since then, applicants' petition for certiorari will not [be granted]. . . .

Miroyan v. United States, 439 U.S. 1338, 1338-39 (1978) (Rehnquist, J., denying application for stay). The Petition provides no reason for this Court to reverse its recent course and grant certiorari here.

II. THE PETITION'S RELIANCE ON A DIFFERENT THEORY OF ANTITRUST LIABILITY FROM THAT ACTUALLY EMPLOYED BY THE COMMISSION BELOW RENDERS THIS CASE INAPPROPRIATE FOR REVIEW

The Petition advances a theory of antitrust liability that was not the basis for the Commission's decision, was not evaluated by the Eleventh Circuit below, and has never been accepted by any Circuit Court. This Court has emphasized in reviewing past FTC orders that, "[o]nce the Commission has chosen a particular legal rationale for holding a practice to be unfair . . . familiar principles of administrative law dictate that its decision must stand or fall on that basis, and a reviewing court may not consider other reasons why the practice might be unfair." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454-55 (1986). *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 246 (1972) (the Court "must look to the [FTC's] opinion, not to the arguments of its counsel, for the underpinnings of its order"). Under these principles, certiorari should be denied.

A. The Commission's Reliance Upon The "Better Settlement" Theory Was Contrary To Settled And Unchallenged Principles Of Antitrust Law

In its opinion below, the Commission advanced a theory that (it thought) would obviate the need to assess the exclusionary potential of the patent. The Commission thus

stated that it would disregard what might have happened in the patent litigation, and focus instead on what might have happened during settlement negotiations. Pet. App. 81a-82a. The Commission expressly rejected the ALJ's conclusion that, "[s]ince complaint counsel did not prove either invalidity or non-infringement, . . . it was not possible to conclude that the settlement agreements in issue delayed generic entry that would otherwise have occurred." *Id.* at 53a. Instead, the Commission reasoned that there was another way to hypothesize generic entry, even if the generic drug would have been infringing:

> The issue is whether [the settlement's] unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates *that would have been agreed upon* in the absence of the payments. We explain below why this question can be answered without an inquiry into the merits of the patent litigation.

Id. at 54a (emphasis added). Thus, the Commission deemed the settlement that the parties actually chose to be anticompetitive because it prevented them from choosing a different settlement that the Commission would have regarded as better for consumers. *Id.* at 82a (agreement was "unreasonable" if it "delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

The Commission's rationale, however, violates a fundamental principle of antitrust law: The requirement that conduct be unreasonably anticompetitive cannot be satisfied simply by positing alternative conduct that would be *more* competitive. As this Court has recently emphasized:

> The Sherman Act is indeed the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.

Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415-16 (2004) (internal quotation marks and citation omitted). The lower courts have long held that an antitrust tribunal may not conclude that "the availability of an alternative means of achieving the asserted business purpose renders the existing arrangement unlawful [because] that alternative would be less restrictive of competition. . . ." *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975). The Second Circuit explained this point in rejecting a claim that blanket licenses in the music industry were more restrictive of competition than other potential licenses:

> Even if the evidence showed that most of the efficiencies of the [challenged] blanket licenses could be achieved under source licensing [the proposed alternative], it would not follow that the blanket license thereby becomes unlawful. The blanket license is not even amenable to scrutiny under section 1 unless it is a restraint of trade. The fact that it may be in some sense "unnecessary" does not make it a restraint.

Buffalo Broad. Co. v. ASCAP, 744 F.2d 917, 933 (2d Cir. 1984).[6]

This principle is undisputed in the courts and unchallenged in the Petition. Even for an alleged monopolist, the antitrust laws impose only the negative duty to refrain from harming competition, not the positive duty to improve it. *E.g., USM*, 694 F.2d at 513 (Posner, J.) ("There is a difference between positive and negative duties, and the antitrust laws . . . have generally been understood to impose

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[6] A less restrictive alternative may become relevant in the final step of a rule of reason analysis, that is, *after* a plaintiff shows an unreasonable restraint and the defendant counters with evidence of procompetitive benefits. But, as the Areeda Treatise warns, such an "[i]nquiry [is] relevant only after [the] threshold showing" of an unreasonable restraint. II Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1913c, at 306 (1988 Supp.).

only the latter."). Accordingly, as long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more palatable." *Ciprofloxacin*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16).

While this established law explains why the Commission's rationale has no judicial support, the "better settlement" theory fails on other grounds as well. The Commission's conclusion that "it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations" is neither persuasive nor supported. Pet. App. 75a. The Commission crucially failed to consider the royalty rate that would accompany any such license with an early entry date. Depending on a variety of circumstances that the Commission ignored, a later entry date with a lower royalty rate could easily benefit consumers more (in the Commission's terms) than an earlier date with a higher royalty. Indeed, the courts recognize that the ability of the settling parties to set a royalty that would not materially lower consumer prices wholly undermines the Commission's conclusion that settlements with licenses are necessarily better for consumers than settlements with payments.[7] As one court recently explained, by choosing from a variety of

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[7] Judge Posner anticipated the same point over 20 years ago, when he explained that multiple licenses were no guarantee of consumer benefit

> if the [licensed] "competitors" were constrained by the terms of the patent license to charge the monopoly price. And they would be. As a rational profit-maximizer [the patentee] would charge its licensees a royalty designed to extract from them all the monopoly profits that the patent made possible; and the licensees would raise their prices to consumers to cover the royalty expense. The price to the consumer would be the same as it is, today, with . . . only [one] seller in the market.

Brunswick Corp. v. Riegel Textile Corp., 752 F.2d 261, 267 (7th Cir. 1984).

licensing terms, "the parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment." *Ciprofloxacin*, 363 F. Supp. 2d at 537 (noting that a license with exclusive geographic territories could accomplish the same result).

Finally, the Eleventh Circuit also rejected the Commission's "better settlement" rationale on factual grounds that the Petition does not contest. The Eleventh Circuit concluded that "[t]here is simply no evidence in the record" to support a conclusion that the parties would have "attained an earlier entry date without the role of payments." Pet. App. 30a. This conclusion was fatal because "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay." *Id.* at 21a. While the Petition now contends that the Commission merely used "a *hypothetical* no-payment compromise as a benchmark" (a contention we discuss below), it does not dispute the absence of any evidence that a "better" settlement would have occurred.

Accordingly, even if the rationale that the Commission actually employed were being defended by the Petition, it would not be appropriate for certiorari. The Commission's rationale was plainly contrary to settled law on which there is no split in the lower courts. Certiorari does not lie to determine whether the Circuit Court correctly applied principles of law that the Petition does not question, nor to consider the existence of substantial evidence that the Petition makes no claim to exist.

B. Because The Commission's New "Probabilistic Property" Theory Has Not Been Accepted By Any Circuit, And Was Not Even Applied By The Commission Below, Review by this Court Is Inappropriate

1. To remedy the weakness of the Commission's actual rationale, the Petition seeks to substitute a new one. The Petition has abandoned the Commission's reasoning in favor

of a theory of "probabilistic property," based on the following propositions: (1) the property right conveyed to a patent is merely "probabilistic" because it consists only of the right to go to Court and "*try* to exclude," Pet. 16; (2) the uncertainty and complexity of all patent litigation mean that there is always some chance that the generic challenger will win the patent suit, *id.*; (3) the "chance" of generic entry in each case must be deemed a consumer property right, *id.* at 14 & 18; and (4) the parties' settlement is therefore anticompetitive unless it conveys to consumers the full value of that property right in the form of a license with an entry date in advance of patent expiration. *Id.* at 18-19.

In support of this rationale, the Petition argues that the Eleventh Circuit's opinion "ignores the most salient factor . . ., the existence of *uncertainty* regarding" the exclusionary effect of the patent. Pet. 15 (original emphasis). That uncertainty, they maintain, "requires that the boundaries of the patent's coverage be delimited . . . ." *Id.* at 16. According to the Petition, when Hatch-Waxman litigants settle, therefore, "the elimination of the *prospect* of competition, even if uncertain, harms consumers." *Id.* at 14 (emphasis added). To illustrate, the Petition asserts that, if "there is a 50-50 chance that a patent holder will prevail in litigation," a settlement that precludes that generic's entry for the life of the patent is anticompetitive because "consumers would lose the 50 percent chance they had of enjoying the benefits of competition." *Id.* at 17-18.

For purposes of certiorari, the initial problem with this rationale is that it cannot be found in the Commission's opinion. The Petition may now assert that "the Commission's analytical approach did not turn on 'the untenable supposition that without a payment there would have been different settlements . . ., resulting in earlier entry dates,'" Pet. 18, but that is precisely what the Commission

said, on multiple occasions.[8] Indeed, the Commission specifically denied that its rationale was related to the "prospect" that one or the other of the litigants would prevail in the litigation:

> We cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact, *we make neither assumption*, but rather focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties *would otherwise have agreed to* in a settlement.

Pet. App. 81a-82a (emphasis added).

Equally as important for purposes of certiorari, the Eleventh Circuit made no reference to, and hence engaged in no analysis of, the "probabilistic" theory. Instead, the Court of Appeals took the Commission at its word: "The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates." Pet. App. 30a. The court below rejected that conclusion both for its flawed "logic," *id.*, and for the (now conceded) lack of evidence to support it. *Id.* at 30a-31a. The underlying merits of the patent litigation, however, whether based on probabilities or expected values of unknown judicial outcomes, were neither mentioned nor evaluated by the Court, because "FTC complaint counsel conceded that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006." *Id.* at 20a.

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[8] The controlling issue, according to the Commission, was whether the settlement payments "delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments." Pet. App. 54a. *See id.* at 82a (agreement was "unreasonable" if it "delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

Certiorari is routinely denied where a given legal doctrine has not been adequately tested and analyzed by the lower courts. That ensures that the Court's review will benefit from the wisdom of those who have considered and applied the doctrine before it. Certiorari is particularly inappropriate where, as here, the proposed rationale has not even been considered in the case for which the writ is sought.

2. The "probabilistic" theory on which the Petition now rests was first advanced by an economist, Professor Shapiro, and has been echoed in a law review article by Professor Hovenkamp and two co-authors.[9] On this basis, the Petition represents that the theory is advanced by "both economists and legal scholars." Pet. 16. But the Petition cites no court decision embracing or even discussing the theory, and for good reason. No circuit court decision has yet to consider it. A few district courts, though not cited in the Petition, have addressed the theory in the Hatch-Waxman context. Judge Posner, sitting by designation as a District Judge and citing both the Shapiro article and the Hovenkamp article, observed that, "[w]hether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass*, 289 F. Supp. 2d at 994. And Judge Trager, moreover, rejected the theory in a detailed analysis, as legally and conceptually flawed. *Ciprofloxacin*, 363 F. Supp. 2d at 531-34.

As these decisions and other critiques of the theory show, it is not yet sufficiently developed to merit review in this Court.[10] As noted, the theory posits that the possibility that

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[9] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

[10] In fact, there is evidence that the probabilistic theory is still developing not only in the Courts, but in the minds of its authors as well. The initial premise of the theory is that "unlike forms of property that are

the generic challenger may win the patent case constitutes a form of "consumer surplus" that the settling parties are obligated to convey through their settlement. *Ciprofloxacin*, 363 F. Supp. 2d at 531. "'Effectively, consumers have a "property right" to the level competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.'" *Id.* (quoting Shapiro, *supra*, 34 RAND J. OF ECON. at 396). The professor put the term "property right" in quotation marks, and rightfully so. As the *Ciprofloxacin* court observed, "there is no support in the law" for the "concept of a public property right in the outcome of private lawsuits." *Id.* In fact, this probabilistic

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defined in terms of title to tangible items," patents are "probabilistic." Pet. 16. Thus, in the Minnesota Law Review, Professors Hovenkamp, Janis, and Lemley state: "As Carl Shapiro has pointed out, a patent is not a right to exclude, but rather a right to *try* to exclude." 87 MINN. L. REV. at 1761 (emphasis added). Yet, the current version of the Areeda Treatise, which also bears Professor Hovenkamp's name, takes a decidedly different approach:

> [A] patent is presumptively not a monopoly at all; it is merely *the right to exclude others* from copying a particular process or product. As such it is *no different from any other property right* — for example, ownership of an airplane or pipeline entails the right to exclude others from using it.

III Areeda & Hovenkamp, *supra*, ¶ 704, at 159 (2d ed. 2002) (emphasis added). This latter observation, while in conflict with the "probabilistic" theory, is in keeping with the mainstream view of patents as property: "Intellectual property is intangible, but the right to exclude is no different in principle from General Motors' right to exclude Ford from using its assembly line, or an apple grower's right to its own crop." Frank H. Easterbrook, *Intellectual Property Is Still Property*, 13 HARV. J.L. & PUB. POL'Y 108, 109 (1990). As Justice Holmes once said, the patentee's right to exclude is the same of that of an "owner of a five acre lot. A patent is property carried to the highest degree of abstraction — a right *in rem* to exclude, without a physical object or content." Letter from Holmes to Pollock, June 26, 1894, in 1 HOLMES-POLLOCK LETTERS: THE CORRESPONDENCE OF MR. JUSTICE HOLMES AND SIR FREDERICK POLLOCK, 1874-1932, at 53 (Harvard Univ. Press 1941).

theory is contrary to several general principles of established law:

First, a patent holder simply has "no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer." *Id.* at 532 (citing *United States v. Studiengesellslchaft*, 670 F.2d at 1127). The notion that a settlement within the scope of a patent's exclusionary effect may still reduce competition because "every patent is 'a little bit invalid' results in undermining the presumption of validity that Congress has afforded patents." *Id.* at 533 (citing 35 U.S.C. § 282).

Second, even more generally, the law does not require private parties acting within the law to shape their agreements to advance the public interest. Thus, the Second Circuit emphatically rejected the argument that a settlement would injure the public interest by preserving a suspect trademark:

> We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.

Nestle Co. v. Chester's Market, Inc., 756 F.2d 280, 284 (2d Cir. 1985).

Third, the probabilistic theory's attempt to substitute the possibility of harm (whether 50%, 10%, or 2%) for actual harm will not suffice to show a violation of the Sherman Act, which requires "an *actual* adverse effect on competition." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). Indeed, no area of the law permits a plaintiff to substitute the possibility of harm for proof of actual harm. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 433B cmt. l (1965) ("A mere possibility of such causation is not enough; and when the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, it

becomes the duty of the court to direct a verdict for the defendant.").[11] Trying to determine in hindsight which party would have prevailed in patent litigation is entirely too speculative to convert possible competitive harm into actual competitive harm. *Ciprofloxacin*, 363 F. Supp. 2d at 531-34 (holding that plaintiffs' theory that but for the settlement the generic challenger would have prevailed in the patent litigation is too speculative to support injury-in-fact).

In addition to these legal problems, others have pointed to the probabilistic theory's theoretical flaws.[12] It purports to be focused on the evil of payments by the patentee, but its reasoning would label settlements employing licenses anticompetitive as well. All settlements remove the "chance" of a generic victory, and the terms of the license may or may not convey *any* "consumer surplus," or at least not enough to suit the FTC. *See Ciprofloxacin*, 363 F. Supp. 2d at 533 ("To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.").

The probabilistic theory is also unworkable in practice. Even if a settlement could properly be measured against the "expected" litigation outcome, that "consumer surplus . . . would first have to be quantified." *Id.* at 532.

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[11] *See In re Bell Petroleum Servs., Inc.*, 3 F.3d 889, 909 (5th Cir. 1993) (proof by less than "'fifty-one percent,' or to the extent of 'more likely than not,' . . . is unacceptably speculative, and amounts to mere *possibility*, not probability") (Parker, J., concurring in part and dissenting in part) (emphasis in original); *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1137 (5th Cir. 1985) ("Possibility alone cannot serve as the basis for recovery, for mere possibility does not meet the preponderance of the evidence standard . . . .").

[12] *E.g.*, Crane, *supra*, 88 MINN. L. REV. at 704; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1060-67 (2004).

Yet even the authors of the articles concede that they cannot account for such elementary factors as asymmetric expectations (the facts that the parties do not agree on the percentage "chance" of losing) and risk aversion (one party's willingness to pay more than another for the same chance of losing).[13] In the end, the probabilistic theory would substitute one inquiry already known to be speculative (who would have won the patent case?) with an inquiry vastly more speculative (what is the percentage "chance" of the patent being defeated to which consumers are entitled?). The resulting negative impact on incentives to settle would be obvious, as "[l]itigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued." *Ciprofloxacin*, 363 F. Supp. 2d at 532.

It is not the obligation of this Court to remedy the flaws and reconcile the inconsistent articulations of the probabilistic theory, when not a single Court of Appeals has addressed it. Certiorari should be denied unless and until the probabilistic theory is adequately addressed and applied by the lower courts, and — as an absolute minimum — actually employed in the case for which certiorari is sought.

CONCLUSION

For the foregoing reasons, the *Amicus Curiae* respectfully requests that the petition for certiorari be denied.

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[13] Shapiro, *supra*, 34 RAND J. ECON. at 397 ("The proper treatment of asymetric information . . . is beyond the scope of this article. Relaxing this assumption leads to a rich area for further research."); *id.* at 410 ("Risk aversion could also be included [in further research].").

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FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORP., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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34 RAND J. Econ. 391 (2003) 8, 9

Statement of Senator Orrin Hatch,
148 Cong. Rec. S7565-01 ..... 10, 11

INTEREST OF THE AMICI CURIAE

The amici states listed on the front cover ("the States"), by their attorneys general, file this brief as friends of the Court on behalf of Petitioner, the Federal Trade Commission ("FTC"). The attorneys general, as the chief law enforcement or legal officials for their respective states, enforce both federal and state antitrust laws and, thus, have a considerable interest in the issues that this case raises before the Court. Specifically, the States have a profound interest in ensuring that the federal antitrust laws are interpreted in harmony with sound antitrust policy and relevant judicial precedent.

In their capacities as *parens patriae*, the States, through their attorneys general, are empowered to protect the consumers in their states from violations of the federal antitrust laws. *See* 15 U.S.C. § 15c. State attorneys general also seek to ensure that consumers have affordable access to the medications that they need.[1] The attorneys general enforce the antitrust laws to ensure that consumers are not denied access to vital health care needs because of artificially high prices resulting from illegal conduct on the part of drug companies.

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[1] In January 2005, Attorney General of Vermont William H. Sorrell, President of the National Association of Attorneys General convened a symposium as part of his Presidential Initiative on Pharmaceutical Pricing. The symposium gathered pharmaceutical experts from government, industry and the private sector to study the benefits as well as the escalating costs of prescription drugs and to seek solutions to the difficulties faced by consumers and government agencies alike in budgeting to cover their rapidly increasing pharmaceutical expenses. In June 2005, Attorney General Sorrell issued his 2005 NAAG Presidential Initiative Report: *Addressing the Cost and Benefits of Prescription Drugs*, available at http://www.naag.org/naag/pdf/20050708-PR-AddressingTheCostAndBenefitsOf PrescriptionDrugs.pdf.

The attorneys general also represent government entities, state agencies and political subdivisions that pay or reimburse for prescription drugs with public funds. The States are struggling to finance state employee drug benefit plans, the prescription drug needs of state hospitals and prisons, injured workers insurance funds and Medicaid and other state pharmaceutical assistance programs.[2] The States spend billions of taxpayers' dollars on pharmaceutical products every year. The State of Maryland, for example, which comprises only about 1.8 percent of the nation's population, spent approximately $710 million in 2004-2005 on prescription drugs for the State's Medicaid and pharmacy assistance program beneficiaries alone.[3]

In these two capacities, as *parens patriae* representatives of consumers and as counsel acting on behalf of the states' proprietary interests, the attorneys general have prosecuted or are pursuing antitrust cases and investigations against pharmaceutical companies that, like the *Schering* matter before the Court, involved reverse payment settlements of patent infringement suits between brand name and generic drug companies.[4] Additionally, the Commonwealth of Pennsylvania currently has an antitrust action pending against Respondents Schering-Plough Corp. and Upsher-Smith Laboratories, Inc.

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[2] NAAG Presidential Initiative Report at p. 93.

[3] Derived from Maryland State Pharmacy Expenditures for Fiscal Year 2005, Maryland Pharmacy Program, Department of Health & Mental Hygiene, unpublished materials on file with the State.

[4] *See, e.g., In re Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich. 2003); *In re Terazosin Hydrochloride Antitrust Litigation*, MDL No. 1317 (S.D. Fla. 2005); *In re Buspirone Antitrust Litigation*, MDL No. 1413 (S.D.N.Y. 2002); *Ohio v. Bristol-Myers Squibb Co.*, Civ. No. 02-1080 (D.D.C. 2003).

alleging the same illegal conduct that is the subject of the FTC's petition.[5] Finally, many states have ongoing non-public antitrust investigations involving several pharmaceutical companies, possible abuses of patent protection and potentially illegal agreements between competitors to deter generic entry. Antitrust prosecutions, settled on behalf of consumers and government purchasers, have resulted in strong injunctive relief and monetary recoveries of hundreds of millions of dollars in overcharges to public and private purchasers of prescription drugs.

SUMMARY OF ARGUMENT

There is an irreconcilable conflict between the Sixth and Eleventh Circuits as to the appropriate antitrust analysis of patent settlements that involve reverse payments, i.e., payments from the patentee to the alleged infringer. This split in legal precedent creates confusion regarding the scope of patent rights and frustrates the consistent enforcement of federal and state antitrust laws. Furthermore, the Eleventh Circuit's decision is analytically unsound and ill-advised because it ignores the statutory balance between intellectual property rights and competition, resulting in harm to consumer and state purchasers of prescription drugs. Finally, the Eleventh Circuit's decision disserves the public interest in two ways. First, the decision nullifies any benefit that would otherwise flow to the public as a result of the settlement of legal disputes. Second, it discourages enforcement of the antitrust laws by requiring litigation of the underlying patent dispute, even before analyzing the anticompetitive effects of the reverse payment settlement. Its test examines (1) the scope of the exclusionary

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[5] *See Pennsylvania v. Schering-Plough Corp.*, Civ. No. 01-328-E (filed Oct. 4, 2001 W.D. Pa.) *transferred to In re K-Dur 20 Antitrust Litigation*, MDL No. 1419 (D.N.J.2001).

potential of the patent; (2) the extent to which the agreements at issue exceed that scope; and (3) the resulting anticompetitive effects. The Eleventh Circuit, thus, articulates a test that is inconsistent with well-settled antitrust principles and precedent; its analysis improperly shifts burdens of proof, thereby making it unduly onerous for antitrust enforcers to mount effective challenges to anticompetitive patent settlement agreements.

ARGUMENT

I. THE ELEVENTH CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH THE SIXTH CIRCUIT'S DECISION ON AN ISSUE OF NATIONAL CONSEQUENCE.

The Eleventh Circuit's holding that reverse payments are, in effect, per se legal directly conflicts with the Sixth Circuit's decision which held that patent infringement disputes settled by reverse payments are per se illegal. This Court's resolution of the conflict is needed not only to provide consistency in the courts, but also to provide guidance to the pharmaceutical industry, state and federal antitrust enforcement agencies and all public and private purchasers of prescription drugs.

Both proponents and opponents of per se antitrust analysis of reverse payment settlements have acknowledged the conflict between the Circuits and have sought the Court's review. On October 12, 2004, the Court denied two pertinent petitions for certiorari. In *In re Cardizem CD Antitrust Litigation*,[6] the Sixth Circuit held that an agreement among parties to a patent infringement suit, whereby the patent owner paid the alleged

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[6] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 125 S.Ct. 307 (2004).

infringer to stay out of the United States market for Cardizem CD and its generic equivalents, constitutes a horizontal market allocation agreement and, therefore, is per se illegal under the Sherman Act.[7] The petitioner, pharmaceutical manufacturer Andrx Pharmaceuticals, Inc., in appealing the Sixth Circuit's finding that reverse payment settlements are per se illegal, argued that the Sixth and Eleventh Circuits reached opposite conclusions on the same issue in indistinguishable cases.[8]

On the same day, the Court denied the petition for certiorari in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*[9] The *Valley Drug* case, decided by the Eleventh Circuit, held that settlement agreements, whereby the patent owner paid the alleged infringers not to enter the United States market for Hytrin, its generic equivalent and other generic terazosin hydrochloride products, are not per se illegal under the Sherman Act.[10] That petition for a writ of certiorari was filed by Louisiana Wholesale Drug Company, Inc. and Valley Drug Company, who were not the parties to the patent infringement settlement, but rather were purchasers allegedly injured by the anticompetitive agreement entered into by the two pharmaceutical companies, Geneva Pharmaceuticals, Inc. and Abbott Laboratories. Unlike the petitioner seeking certiorari in the *Andrx* case, the petitioners in *Valley Drug* argued that the court of appeals erred in failing to apply the per se rule to

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[7] 332 F.3d at 908-09.

[8] *See* Petition for a Writ of Certiorari, *Andrx Pharms.*, 2003 WL 22867750 at *2,*8-*12.

[9] 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004).

[10] *Id.* at 1309-10.

reverse payment settlements of patent disputes.[11] Nevertheless, petitioners in *Valley Drug* also acknowledged the split between the Sixth and Eleventh Circuits in indistinguishable cases addressing the same issue.[12] Thus, both sides of the debate, those favoring per se treatment and those opposing it, have acknowledged the conflict between the Circuits and have requested the Court's guidance in resolving it.

This case involves a third antitrust challenge to agreements between parties in a patent infringement suit where the patent owner paid the alleged infringers not to enter the U.S. market for a branded drug, here K-Dur 20, and its generic equivalents. Given the Eleventh Circuit's decision in *Valley Drug*, it came as no surprise that Schering-Plough and Upsher-Smith Laboratories, Inc. chose that forum in which to file their appeal of the FTC's ruling against them. Indeed, the Eleventh Circuit went beyond its holding in *Valley Drug* and ruled that reverse or exclusion payments from the patent owner to the alleged infringer are not only *not per se illegal*, but further are fully within the potential exclusionary power of the challenged patent and therefore, in effect, *per se lawful*.[13] More troubling

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[11] *See* Petition for a Writ of Certiorari, *Valley Drug*, 2004 WL 322428 at *19-*24.

[12] *Id.*

[13] See *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 at 1075-76 (11th Cir. 2005). In its petition, the FTC does not contend (and the States do not here assert) that the Eleventh Circuit erred in failing to apply the per se rule to the K-Dur 20 agreements. Instead, the States highlight the Circuit conflict in order to stress the urgency of the need for the Court's review of patent settlement agreements that raise antitrust implications, especially those that involve reverse payments and even more critically, those that purport to resolve the patent infringement dispute within the

still, the court of appeals held that before any anticompetitive effect of the settlement could be measured, the antitrust plaintiff must first litigate the merits of the underlying patent dispute.

Before the Eleventh Circuit's *Schering* opinion, some questioned whether the Circuits were truly split as to the appropriate antitrust analysis of reverse payments settlements.[14] Today, however, no doubt exists that the issue is ripe for the Court's review.[15] The Sixth Circuit and the Eleventh Circuit cannot both be correct. In fact, at least in the context of an agreement that resolves the patent dispute within the patent's potential term and scope, some would argue that neither analysis adequately balances the competing interests represented at the intersection of intellectual property law and antitrust principles, further indicating the need for the Court's review. The States request that the Court grant the FTC's petition and resolve this irreconcilable conflict between the Circuits.

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potential term and scope of the challenged patent.

[14] *See, e.g.*, Brief for the United States as Amicus Curiae, *Andrx Pharms. v. Kroger Co.*, 125 S. Ct. 307 (2004), 2004 WL 1562075 at *11-*16.

[15] Even counsel for Respondent Schering-Plough Corp. acknowledged the conflict between the Sixth and Eleventh Circuits (months before the Eleventh Circuit's *Schering* decision), characterizing the range in the two courts' treatments of reverse payment settlements as "from per se condemnation to virtual per se legality." *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1039 (2004).

II. THE ELEVENTH CIRCUIT'S DECISION SUBVERTS THE PURPOSE AND EFFECT OF THE HATCH-WAXMAN ACT AND INJURES CONSUMERS AND GOVERNMENT PURCHASERS.

In the past five years, there has been an explosion of academic commentary addressing the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), also known as the Hatch-Waxman Amendments to the Federal Food, Drug & Cosmetic Act ("Hatch-Waxman"), and the antitrust implications of patent infringement settlements involving reverse payments.[16] Federal

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[16] *See, e.g.*, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Applications*, 54 Fla. L. Rev. 747, 752 (2002); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L.J. 777 (2003); Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?*, 64 U. Pitt. L. Rev. 201 (2002); Marcy Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purpose of the Hatch-Waxman Act*, 50 Emory L.J. 1331, 1353 (2001); Kevin D. McDonald, *Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea*, 15 Antitrust Health Care Chron. (ABA Section of Antitrust Law Newsletter) 2, 12-13 (2002); Kevin D. McDonald, *Hatch-Waxman Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, Antitrust, Spring 2003, at 68; Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1767 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34

courts have struggled with these complex, yet critical issues, resulting in confusing and inconsistent rules of law. While opinions diverge widely on what the law should be with regard to reverse payments, amidst the lively debate, there is serious doubt that the Eleventh Circuit's approach in *Valley Drug* and *Schering* is compatible with the provisions of the Hatch-Waxman Act that promote generic competition.[17]

By enacting Hatch-Waxman, Congress intended not only to preserve valid and enforceable patent rights, but, at the same time, to expedite the availability of generic alternatives to brand name prescription drugs. Hatch-Waxman encourages generic entry by (1) permitting the generic drug applicant to rely on the safety and efficacy studies performed by the brand name drug pioneer in obtaining FDA approval; and (2) encouraging generics to challenge weak or dubious patents as invalid or not infringed by awarding the first successful challenger 180 days of marketing exclusivity. 21 U.S.C. § 355 (j)(5)(B)(iv)(1984), *amended by* 117 Stat. 2066, Pub.L. 108-173 § 1102 (2003). In the House Report recommending adoption of the Act, the House Committee on Energy and Commerce noted the cost savings to federal and state governments as the result of additional generic entry. After noting that the availability of a generic alternative for one drug had saved the Department of Defense $1.2 million, the Committee said, "Federal and state governments will be denied comparable savings on drugs approved after 1962 because of the lack of an approval procedure [for new generic drugs]." H.R. Rep. 98-857 (I), at 17,

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RAND J. Econ. 391 (2003).

[17] *See, e.g.*, Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments; Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 Antitrust L.J. 1069(2004).

1984 U.S.C.C.A.N. 2647, 2650.

In contrast to the goals set forth in Hatch-Waxman, the Eleventh Circuit's decision not only fails to encourage generic entry, it affirmatively supports collusive resolutions of patent infringement challenges. Specifically, the Eleventh Circuit decision allows Hatch-Waxman to be manipulated to shield payments from one competitor to another in exchange for the second competitor's forbearance in entering the market. If the Eleventh Circuit were correct, generic entry following a patent challenge would be rare. In virtually all cases, the patent owner can afford to pay the generic challenger more to drop its challenge and exit the market than the generic could make marketing its product. In other words, if the patent owner's potential loss exceeds the generic challenger's potential gain, it will be in both parties' mutual best interest to settle the case by dividing up monopoly profits. While it is a win-win situation for the pharmaceutical companies, the big losers are the victims of antitrust violations: the end-payor purchasers of prescription drugs, primarily consumers, government agencies and healthcare benefit plans.

When Congress amended the Hatch-Waxman Act in 2003, it cited as one reason for legislative reform that the unusual configuration of interests and incentives created by the statutory scheme had the unintended consequence of enticing brand and generic drug companies to enter into potentially anticompetitive settlement agreements.[18] Among the corrective provisions

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[18] *See* 148 Cong. Rec. 7565-01, S7566 (2002) (Statement of Senator Orrin Hatch, Senate Floor Debates on the Greater Access to Pharmaceuticals Act, S. 812) ("As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling.... We did not wish to encourage situations where

enacted to curtail anticompetitive abuses is the requirement that brand and generic drug companies entering into patent litigation settlements submit those settlements to federal antitrust enforcers for review.[19] These reviews of patent settlements by antitrust agencies are likely to be of marginal effectiveness in ensuring compliance with the antitrust laws if government challenges of those agreements are held to the incorrect and overly burdensome standards set forth by the Eleventh Circuit.

The benefits that Congress intended to bestow upon purchasers of prescription drugs in this country through Hatch-Waxman are needed now more than ever before. Innovations in pharmacological research, which deserve appropriate marketing protection by proper interpretation of the patent laws, have led to an increased ability to treat many medical ailments pharmaceutically.

Every year, this country spends more than $100 billion on prescription drugs and those expenditures are rising rapidly.[20]

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payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.... However the K-Dur case ultimately is decided, I commend [the FTC for continuing its] policy of zealously reviewing these types of reverse payment cases to determine whether such agreements run afoul of the antitrust laws").

[19] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 117 Stat. 2066 §§ 1111-1118.

[20] Spending in the U.S. increased an average annual rate of 14.5% from 1997-2002. *See* Congressional Budget Office, *Would Prescription Drug Importation Reduce U.S. Drug Spending?* (April 29, 2004). According to the Centers for Medicare and Medicaid Services, pharmaceutical expenditures rose 14.9% in 2002 and 10.7% in 2003. Center for Medicare & Medicaid Services,

For example, in 2002, nationwide expenditures for prescription drugs totaled over $160 billion.[21] However, not only is the country buying more drugs, pharmaceutical prices continue to rise as well. During the decade from 1993-2003, retail prescription drug prices increased an average of 7.4 percent per year, nearly three times the average yearly inflation rate of 2.5 percent during the same time period.[22] Moreover, the prices for drugs claiming patent protection continue to rise at an alarming rate relative to the increase in price for generic substitutions. The cost of brand name prescription drugs has been rising steadily at twice the rate of inflation, while the cost of generics is increasing at the rate of less than 1 percent.[23]

The FDA has estimated that consumers and state agencies can save at least 50 percent on their pharmaceutical needs by

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Highlights-National Health Expenditures, 2003 at 1 (January 11, 2005) ("CMS, *Highlights*"). In the twenty years since Hatch-Waxman was enacted, while healthcare spending has increased dramatically overall, expenditures for prescription drugs have remained the fastest growing component. *See* The Henry J. Kaiser Family Foundation, *Prescription Drug Trends* at 1 (Oct. 2004); Stephen Heffler et al., *Health Spending Projections Through 2013*, Health Affairs Web Exclusive, Feb. 11, 2004.

[21] *See Prescription Drug Trends* at 1 (Oct. 2004)

[22] *Id.*; CMS, *Highlights*.

[23] A survey of wholesale prices conducted by AARP and published in August 2005, showed that a 12-month average increase for 195 brand name drugs was 6.6% or more than double the 3.1% rise in the Consumer Price Index that monitors general inflation rates. *See* David Gross, et al., *Trends in Older Americans-First Quarter 2005 Update, AARP Public Policy Institute* (July 2005), available at http://www.assets.aarp.org/ rgcenter/health/dd122_ drugprices.pdf.

purchasing generic products.[24] Generic drugs acquire, on average, 44 percent of sales from bioequivalent brand name drugs during the first year after generic entry.[25] Timely availability of these products is key; each day that generics are illegally kept out of the market represents millions of dollars in unwarranted overcharges for consumers and government payors. In 1994 alone, consumers saved between $8-10 billion by purchasing generic versions of brand name drugs.[26]

The prompt availability of generic alternatives is increasingly important as more and more states enact laws and promulgate regulations mandating generic substitution, pharmaceutical formularies and preferred drug lists,[27] and institute supplemental pharmaceutical assistance programs to provide affordable access to prescription drugs for their citizens.[28] At the federal level, expedited access to generic drugs

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[24] *See* U.S. Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004).

[25] *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xii (July 1998) ("CBO 1998").

[26] *See* CBO 1998 at ix.

[27] The enforcement of state laws designed to promote the utilization of generic drugs is further frustrated by the Eleventh Circuit's decision. *See e.g.*, National Conference of State Legislatures, 2005 Prescription Drug State Legislation Mid-Year Edition: August 15, 2005, available at http://www.ncsl.org/programs/health/drugdisc05.htm (NCSL 2005 Prescription Drug State Legislation")

[28] As of May 2005, at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to the low-income elderly or to persons with disabilities who do not qualify for Medicaid. *See* NAAG Presidential Initiative Report at p. 93; NCSL 2005 Prescription Drug State

takes on an even greater fiscal urgency as the country finalizes plans to provide Medicare beneficiaries with drug benefits in January 2006 under the Part D program.[29] If generic drugs are not made available in the manner intended by Hatch-Waxman, these already costly government programs may quickly become cost-prohibitive.

The need for the Court's guidance is crucial and the FTC's petition comes at a critical time. Many expensive brand name drugs--at least 60 percent of the fifty top-selling brands--are currently facing patent challenges from generic competitors as contemplated and, indeed, encouraged by Hatch-Waxman.[30] The Eleventh Circuit's decision, however, frustrates the statute's

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Legislation.

[29] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

[30] For example, eighteen of the thirty top-selling brand name prescription drugs are subject to patent challenges by generic competitors. Manufacturers of Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax Risperdal, Zoloft, Zocor, Pravachol, Actos, Aciphex, Levaquin and Lovenox have all received abbreviated new drug application paragraph IV certifications from generic drug competitors challenging the validity and/or enforceability of the brand name drugs' patent protection. *See, e.g.*, NDC Health Corporation, The Top 200 Prescriptions for 2004 by U.S. Sales (Mar. 2005) available at http://www.ndchealth.com/press_center/uspharamaindustrydata.asp; FDA Center for Drug and Evaluation and Research, Paragraph IV Patent Certifications as of August 15, 2005, U.S. Food & Drug Administration, (created Feb. 16, 2005, updated August 15, 2005) available at http://www.fda.gov/cder/ogd/ppiv.htm

intent by articulating a test that not only discourages generic entry, but also promotes unwarranted extension of patent rights and the division of monopoly profits by pharmaceutical companies, at the expense of American consumers. The Court's analysis is needed to ensure that the provisions of Hatch-Waxman, both those that promote innovation by protecting patent rights, as well as those that accelerate generic competition, are not circumvented by errors in judicial interpretation.

III. THE PUBLIC INTEREST IS DISSERVED BECAUSE THE ELEVENTH CIRCUIT'S DECISION DISCOURAGES ANTITRUST SCRUTINY OF PATENT SETTLEMENT AGREEMENTS.

Antitrust enforcers, patent infringement litigants and the courts agree that "public policy wisely encourages settlements" of legal disputes. *McDermott Inc., v. AmClyde*, 511 U.S. 202, 215 (1994). Patent litigation, particularly in areas involving complex technical issues like those involved in the pharmaceutical industry, is extremely expensive for the parties and burdensome for the courts. When a legal dispute is pursued through trial, the expenses of litigation are passed on to the public in the form of increased prices of products and services provided by both parties. In the ideal case, settlement avoids these costs and allows the parties in pharmaceutical patent disputes to focus on ways of inventing, producing and marketing new medications, for the benefit of the public.

However, not all settlements are actually in the public interest. If the patent settlement results in an unlawful extension of monopoly rights, the public interest requires challenging that

settlement under the antitrust laws. In reviewing the FTC's antitrust challenge of the patent infringement settlements at issue in this case, the Eleventh Circuit devised a three-part test that mandates an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. *Schering-Plough v. Federal Trade Commission*, 402 F.3d 1056, 1066 (11th Cir. 2005). This test not only vitiates the purported benefit to the public from the patent settlement (i.e., avoidance of lengthy and expensive trial and concomitant increase in the price of pharmaceutical products), but also deters enforcement of the antitrust laws to the further detriment of the public good. In order to prove an antitrust challenge, an antitrust prosecutor or plaintiff must first prove the invalidity and/or noninfringement of the underlying patent. The Eleventh Circuit's decision disserves both the public interest favoring settlement of legal disputes and the public interest in ensuring compliance with the antitrust laws.

Although the Eleventh Circuit does not expressly advocate a *post hoc* analysis of patent validity and/or infringement, that is precisely what its three-part approach requires. The Eleventh Circuit has erroneously extended the statutory presumption of *validity* of the patent[31] to an unprecedented and unwarranted presumption of *infringement* of that patent. The Eleventh Circuit's decision reassigns the burdens of proof (1) from the generic challenger to the government to show that the patent is invalid; and (2) from the patent owner to the government to

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[31] 35 U.S.C. §282.

show that the patent is not infringed,[32] before any settlement of the patent challenge may be scrutinized under the antitrust laws.[33] According to the Eleventh Circuit, if antitrust enforcers do not rebut those presumptions by showing invalidity of the patent and/or that the patent litigation was a sham, then the scope of the exclusionary potential of the patent is deemed to be that of the patent, had it been judicially determined valid and infringed. *Id.* at 1068. In other words, if the patent is presumed valid and infringed, and the antitrust enforcer fails to prove otherwise, then the exclusionary potential is the full term and scope of the patent, and a division of monopoly profits between the patent owner and the generic challenger is deemed justified as within those parameters. *Id.* at 1074-76. The illogic of this circular reasoning is manifest in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), where the district court, relying in large part on the Eleventh Circuit's analysis, expressly concluded that reverse payments are legal, and also tacitly concluded that the weaker the patent

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[32] The Eleventh Circuit erroneously stated that "Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products... did not infringe Schering's patent." *See* 402 F.3d at 1066-67. The correct burden of proof in a patent dispute is upon the *patentee* to show by a preponderance of the evidence that a competitor's product infringes his patent. *See, e.g., Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997).

[33] This analysis assumes that the Eleventh Circuit would even permit the antitrust enforcer to rebut the twin presumptions of validity and infringement; *Valley Drug* can be also read to exclude any *post hoc* determinations except in cases of fraud or sham litigation. See *Valley Drug*, 344 F.3d at 1309.

owner believes his patent to be, the more he is willing to pay a competitor not to challenge it. *Id.* at 534.

If the patent infringement dispute must be litigated as a prerequisite to any attempt to define the parameters of the patent's authority to exclude, then any efficiencies realized as a result of the patent settlement would inure, if at all, only to the parties to the settlement.[34] Moreover, if the antitrust plaintiff must first prove invalidity and/or noninfringement, many unlawfully anticompetitive settlements will go unchallenged.

The appropriate analysis of an antitrust challenge of a patent infringement settlement, therefore, assesses the strength of the patent in the context of the infringement settlement itself. This is true regardless of whether the settlement includes a reverse payment and regardless of whether reverse payments are deemed per se illegal. Underlying this analysis is the question whether, given the terms of the settlement, it is more likely than not that the patent would have been found (1) invalid and/or unenforceable; or (2) valid and enforceable, but not infringed. In such an analysis, the presence of a reverse payment is but one indicator of the strength or weakness of the patent at issue. Thus, if a patent settlement includes a substantial payment to the generic challenger, "absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for

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[34] Ironically, the Eleventh Circuit relied upon the public policy preference for settlement of legal disputes, citing the benefits of cost savings to the parties and to the public when it articulated its antitrust test. The Eleventh Circuit's test requires litigation of the patent dispute in any event, resulting in cost savings to no one. 402 F.3d at 1072-73, 1075.

the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[35] Further, a patent settlement that resolves a dispute with money rather than with time[36] would indicate a relatively weak patent claim and the more substantial the payment, the weaker the patentee's case is likely to be.[37]

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[35] *See* FTC Petition for a Writ of Certiorari at p.18. ("FTC Pet.")

[36] As the FTC noted in its Petition, patent settlements permitting earlier generic entry instead of payment to the generic challenger are beneficial or at least neutral to purchasers of prescription drugs. *See* FTC Pet. at p.18. The States do not advocate that patent settlements are improper unless they benefit the public, but rather that the Eleventh Circuit's ruling erroneously approves settlements that directly thwart the public interest.

[37] Judicial tests based upon probability are well-established in many areas of the law, including intellectual property and antitrust. For example, preliminary injunctions, frequently applicable to patent infringement disputes, require a showing of probable success on the merits. *See, e.g., Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Clayton Act merger challenges also rely on probability, i.e., the challenger carries a burden of proving a reasonable probability that the transaction would substantially lessen competition. *See, e.g.*, 15 U.S.C. §18; *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962). Proof of negligence takes into account the gravity of the harm, discounted by its improbability, and balances that against the burden of adequate precaution. *See*, e.g., *Red Star Towing & Transportation Co. v. Woodburn*, 18 F. 2d 77 (2d Cir. 1927). In environmental cases, remedial orders essentially weigh the probability and severity of imminent and substantial endangerment within the meaning of 42 U.S.C. §§ 6973, 9606 against the costs of fixing the problem. *See, e.g., United States v. Seymour Recycling Corp.*, 554 F.Supp 1334, 1337-38 (D. Ind. 1982).

The Eleventh Circuit failed to provide a reasoned analysis that would permit antitrust scrutiny of patent settlements, short of trial on the merits of the underlying patent dispute. Such analysis misconstrues and misallocates the appropriate burdens of proof. Moreover, in so doing, it countermands any societal benefit inherent in the policy favoring settlement of legal disputes in the first instance and discourages fair and efficient enforcement of the antitrust laws. Both results run counter to the public interest and disrupt the appropriate balance struck by Congress between enforcement of intellectual property rights and enforcement of the antitrust laws.

CONCLUSION

For the reasons stated, the Federal Trade Commission's petition for a writ of certiorari should be granted.

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IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

MOTION OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AND BRIEF OF *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE*

The National Association of Chain Drug Stores ("NACDS") hereby moves, pursuant to Supreme Court Rule 37.2, for leave to file a brief as *amicus curiae* in support of the petition for a writ of certiorari to the United States Court of Appeals for the Eleventh Circuit. Petitioner Federal Trade Commission has consented to the filing of this brief, but respondents Schering-Plough and Upsher-Smith have declined to consent. A copy of the proposed brief is attached.

NACDS is an association of nearly 200 retail pharmacy chains. NACDS members operate more than 36,000 retail community pharmacies and dispense approximately 70% of Americans' prescription drugs. NACDS members and their customers are directly affected by the anticompetitive practices challenged in this case because those practices maintain artificially high prices for prescription drugs. Accordingly, NACDS is uniquely positioned to address the effect of those anticompetitive practices and to aid the Court in considering the Petition.*

The FTC decision at issue here applied well-established economic principles to the real marketplace facts that were confronting the parties to the patent litigations at the time of their agreements. The payments from Schering to Upsher and ESI must have reduced competition to a level below that expected (absent the payments) by both Schering and those patent challengers. Otherwise, the challengers would not have required those payments in settlement, and Schering would not have made them. The FTC's competitive baseline, against which it measured the amount of

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* Over the past few years, NACDS has filed amicus briefs in several cases involving similar issues, including the appeals in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), and *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 350 F.3d 1181 (11th Cir. 2003), and in the administrative proceedings in this case.

competition that the settlement agreements actually provided, was the amount of competition that the parties themselves expected (*i.e.*, their views of the probability-adjusted amount of competition). That competitive baseline is consistent with that long used by the Courts to determine the legality of intellectual property settlements. *See, e.g., Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963) (White, J., concurring); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 60-61 (2d Cir. 1997).

In contrast, the Court of Appeals panel's competitive baseline was based on the formalistic, and erroneous, proposition that "Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent." Pet. App. 18a. The Court of Appeals erred as to who has the burden of proving both infringement and (at least on the facts of this case) validity. And the whole notion of premising an antitrust analysis on legal presumptions rather than on an economic analysis of real marketplace facts turns back the clock on the progress that antitrust analysis has made in the last 30 years. Premising the antitrust analysis on this particular legal presumption — the rebuttable presumption of validity — is particularly inappropriate because that presumption is one small piece of a larger patent system in which patents are issued *ex parte* and are subject to plenary review in the courts. Courts find more than half of all litigated patents to be invalid. In the pharmaceutical arena, Congress has not only made court review plenary, but has offered a bounty for successful generic challengers. The generic's success rate — despite the presumption relied on by the panel — is greater than 70%. Thus, the panel's analysis, premised as it is on one tiny aspect of the patent system, does not capture the economic reality faced by the parties at the time that they entered their agreements. Moreover, there is abundant additional evidence that Congress never intended the

rebuttable presumption of validity to have the ironclad exclusionary effect that the panel's decision would bestow on it.

The Court should grant review of the panel decision because it is deeply flawed. As a result of 15 U.S.C. § 45(c), that decision, if left unreviewed, would disable the FTC from enforcing the antitrust law against agreements that threaten enormous consumer harm in this vitally important segment of the economy.

Moreover, the panel decision is at odds with that of the Court of Appeals for the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S. Ct. 307 (2004). That Court adopted a competitive baseline similar to that adopted by the FTC, holding that, contrary to the panel decision here, a patent does not create an "'impenetrable' legal impediment to [the generic challenger's] production and sale of its FDA-approved generic product." *Id.* at 914. If the real economic effect of a patent were to provide such ironclad exclusion, then the brand manufacturer "would not have paid [the generic competitor] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. Unlike the FTC, the Sixth Circuit believes that such exclusion payment agreements are so unlikely to ever confer any procompetitive benefits that they should be condemned as *per se* unlawful. Review by this Court is necessary to ensure that the Eleventh Circuit's ruling – starkly at odds with that of another circuit – does not dictate FTC enforcement policy on this important issue.

NACDS respectfully requests that the Court grant leave to file the attached *amicus curiae* brief in support of the Petition.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The National Association of Chain Drug Stores ("NACDS") is a non-profit association of nearly 200 retail pharmacy chains. NACDS members operate more than 36,000 retail community pharmacies and dispense approximately 70% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practices at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore submits this *amicus curiae* brief in support of the petition for writ of certiorari to the United States Court of Appeals for the Eleventh Circuit.

The Court of Appeals panel held that the patentee lawfully paid challengers to withdraw their challenges to the patent and to stay out of the market. Pet. App. 34a-35a. If left standing, that decision would undermine a careful statutory scheme in which Congress sought to rid the pharmaceutical marketplace of weak or narrow patents that block generic entry. Given the enormous consequences for consumers – consumers whose elected representatives reached a starkly different balance between the interests of patent holders and consumers – review by this Court is appropriate.

BACKGROUND

Background of the FTC's Decision

As the 1990s came to a close, consumers stood to benefit from a significant increase in competition between branded and generic pharmaceuticals. More than 40 brand drugs with over $16 billion in annual sales were scheduled to lose patent protection by 2002. Elyse Tanouye & Robert Langreth, *Time's Up: With Patents Expiring on Big Prescriptions, Drug Industry Quakes*, WALL ST. J., Aug. 12, 1997, at A1. And the outlook for

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1. No counsel for a party authored any portion of this brief. No person or entity, other than the named *amicus* and its counsel, made any monetary contribution to the preparation and submission of this brief.

branded drugs beyond 2002 was even dimmer. *See* Theresa Agovino, *Drug Patents Gets Attention of Regulators*, PITT. POST-GAZETTE, Jan. 24, 2002, at E4 (estimating that between 2000 and 2005 one-third of the prescription medicines in the United States, worth more than $30 billion in sales, would lose patent protection). At the same time, there was a dearth of new branded product development. *See, e.g.*, Peter Young, *Troubling Times for Pharma*, 164 CHEMICAL WK. S20 (Sept. 18, 2002) (noting "the widespread problem of weak drug development pipeline profiles among the large branded pharmaceutical companies").

The brand manufacturers responded by employing various "evergreening techniques," *i.e.*, tactics designed to extend exclusivity beyond the patent term or to otherwise impede generic entry. These techniques included improperly listing patents in the Orange Book in order to take advantage of the Hatch-Waxman Act's automatic 30-month stay on generic market entry;[2] switching the product formulation (*e.g.*, from a tablet to a capsule) before a generic enters the market;[3] and restricting ingredient access.[4]

Another such technique was to simply pay the generic challenger to stay out of the market – the "exclusion payment" technique at issue in this case. Some brand manufacturers made such payments to generic manufacturers that were

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2. *See, e.g., In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (improper listing); *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1, 23-24 (D.D.C.), *rev'd*, 268 F.3d 1323 (Fed. Cir. 2001) (improper listing); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 934-36 (N.D. Ill. 1995) (late listing); *FTC v. GlaxoSmithKline*, 202 F.R.D. 8 (D.D.C. 2001) (improper listing).

3. *See FTC Investigates Replacement of Branded Rx With Similar Versions*, FDA Week, Sept. 2, 2005, at § 35 (detailing the FTC investigation into "the practice among brand name drug companies of withdrawing their products shortly before generic competition and introducing slightly different versions").

4. *See, e.g., Eli Lilly & Co. v. American Cyanamid Co.*, No. IP 95-536-C, 2001 U.S. Dist. LEXIS 212, at *4 (S.D. Ind. Jan. 8, 2001) (manufacturer allegedly prevented generic competition by tying up manufacturing capacity).

challenging the validity (or non-infringement) of the brand patent – challenges that Congress expressly encouraged in the Hatch-Waxman Act by granting a bounty for successful challenges. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (granting 180 days of generic market exclusivity to the first ANDA IV filer); *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 629 (D.C. Cir. 2002) (acknowledging the strong incentive created by this exclusivity). In a comprehensive review of all ANDAs filed between 1992 and 2001, an FTC study found that, of the 53 patent infringement cases that had been resolved in that timeframe, 20 settled and 30 were litigated to resolution.[5] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at 16 (July 2002). Among the 20 settlements, 9 included either a supply agreement or a license and 9 included exclusion payments. *Id.* Of the litigated cases, 73% were resolved in favor of the generic challenger. *Id.*

In connection with a consent decree obtained in one of the early exclusion payment cases, the FTC announced that "[p]harmaceutical firms should now be on notice . . . that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues with a potential for serious consumer harm." *Abbott Labs. and Geneva Pharms.*, No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at* http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm. After that announcement, pharmaceutical manufacturers stopped entering into exclusion payment settlement agreements. *See* FEDERAL TRADE COMMISSION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICAID PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 4 (Jan. 2005). Since that time, generic manufacturers have instead either negotiated settlements that include early entries via licenses or continued to litigate their cases. *Id.*

5. In the remaining 3 instances, the cases were resolved either because the patents expired before the expiration of the 30-month stay or the NDA was withdrawn for safety reasons.

The FTC's enforcement efforts in these exclusion-payment cases are vital to this industry. The enormous consumer gains resulting from generic entry – whether by winning the patent litigation or obtaining licensed entry through settlement – are shown by a few examples. Barr Laboratories challenged the patents protecting Eli Lilly's drug Prozac. In the midst of that patent challenge, Barr stated that it would settle only if the agreement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, FORTUNE, Aug. 2001, at 5. Lilly refused the demand because "such a settlement violated antitrust laws, and it isn't morally right." *Id.* (quoting Lilly CEO). So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Similar consumer savings result when generics enter before the conclusion of patent litigation. For instance, in 1998, several generic manufacturers filed ANDAs seeking to market generic versions of AstraZeneca's Prilosec. Although the patent on the chemical entity expired in October 2001, AstraZeneca claimed that the proposed generic products infringed various formulation patents, the last of which is slated to expire in 2007. *See Astra Aktiebolag v. Andrx Pharm.*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002). In October 2002, the district court ruled that generic manufacturer KUDCo's product did not infringe AstraZeneca's patents. *Id.* at 433. Two months later – and over four years before the relevant patents were to expire – KUDCo launched generic Prilosec at a 20% discount to the brand. Susan Jaffe, *Medicaid Hopes to Save Millions With Generic Pill*, CLEVELAND PLAIN DEALER, Dec. 14, 2002, at B2. Generic Prilosec quickly captured 60% of the $3 billion market, resulting in consumer savings of at least $360 million per year. *See* AstraZeneca PLC, First Quarter Results 2003 at p. 2, *available at* http://www.astrazeneca.com/sites/7/imagebank/

migratedpress/q12003narrative.pdf. The Federal Circuit ultimately affirmed the district court's ruling in December 2003. *See In re Omeprazole Patent Litig.*, 84 Fed. Appx. 76 (Fed. Cir. 2003).

By way of another example, GlaxoSmithKline ("GSK") was in the midst of litigating its Paxil patents against generic challenger Apotex when the Hatch-Waxman 30-month stay (21 U.S.C. § 355 (j)(5)(B)(iii)) expired. GSK then sought an injunction to preclude Apotex from the market until the litigation concluded, but the court denied that request. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003). Apotex launched its generic Paxil product in September 2003 – over three years before the Paxil patents were slated to expire. *See* Press Release, Apotex Corp., Apotex Launches First Generic Version of Paxil: Affordable Product Kept from Consumers for Years Too Long! (Sept. 8, 2003), *available at* http://www.apotex.com/PressReleases/20030908-01.asp. In April 2005, the Federal Circuit affirmed judgment in favor of Apotex, ruling that GSK's patent is invalid. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). We estimate that the savings to consumers from September 2003 until April 2005 (when the patent litigation concluded) were more than $1 billion; the savings from September 2003 until December 2006 (when the patents would have expired) will exceed $ 2 billion.[6]

None of these consumer savings would likely have occurred if the Court of Appeals panel's ruling had been the law at the time. If exclusion payments are permissible under the antitrust law – if the CEOs of Lilly and the other manufacturers are told that they are *wrong* to believe that an exclusion payment settlement "violate[s] antitrust laws, and it isn't morally right" – such settlements will very likely become the norm. The vast majority of pharmaceutical patent cases can be settled. Keith Leffler et al., *Efficiency Trade-Offs in Patent Litig. Settlements: Analysis Gone Astray?*, 39 U.S.F.L. Rev.

6. We assume an averaged generic penetration rate of 75%, a generic discount of 45% off the brand price, and a market of $2 billion per year (at the brand price).

33, 42 (Fall 2004).[7] The wide disparity between the profits gained by a generic challenger and the profits lost by the brand manufacturer when a generic enters allows for a wide range of settlement possibilities. *Id.* Even if a generic challenger believes that there is a 100% chance that the patent will be found to be invalid, the case can nevertheless be settled with an exclusion payment if the patentee believes that there is anywhere from a 6% to a 100% chance of invalidity. *Id.* Moreover, of the cases that can be settled, both the brand and generic manufacturer have a strong economic incentive to divide the monopoly profits between themselves by means of an exclusion payment rather than to share those profits with consumers by means of licensed generic entry. *Id.* at 44. So, except in the rare instance in which each party believes that he is virtually certain to win, pharmaceutical patent cases can always be settled, and both parties' economic incentive is to settle with an exclusion payment rather than licensed entry.

The FTC Decision And Its Rationale

The unanimous FTC decision applied well established law and economic principles to determine the competitive effects of a patentee's paying cash to its rivals in exchange for withdrawing a patent challenge and staying out of the market. The key marketplace fact is that, as of the date of the agreements at issue,[8] it was *uncertain* whether Upsher and/or ESI would succeed in their efforts to compete with Schering. Upsher and ESI might have lost the patent litigations, but they also might have won.

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7. Of course, not all pharmaceutical patent cases that can be settled are in fact settled. Factors extraneous to the merits of a particular case sometimes make settlement unattractive to one or more of the parties. For example, the patentee lacks incentive to settle if he has another entry-defeating tactic in reserve in the event of a loss in the patent litigation. See Complaint, *CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al.*, No. 05-340-KAJ (D. Del. Aug. 17, 2005) (alleging that by the time patentee had lost patent litigation, patentee had switched branded product from capsules to tablets, thus preventing FDA from approving A-B-rated generic).

8. The legality of an agreement under the antitrust laws is determined as of the date that the agreement was entered into. *See, e.g.*, XI Herbert Hovenkamp, ANTITRUST LAW ¶ 1901, at pp. 185-86 (1998); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir. 1981).

The uncertainty as to Schering's ability to prevent Upsher's and ESI's entry was substantial. The principal issue in both litigations was whether the generic products infringed Schering's patent. Infringement determinations are inherently fact intensive and subject to great uncertainty. Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1934 n.179 (2002) ("the effort to map the words of patent claims to products is inherently an uncertain one"); *see also* Richard J. Gilbert & Willard R. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 47 n.8 (2001) ("the boundaries of intellectual property defy accurate survey to a much greater extent than do those of tangible property"). Both litigations also involved assertions of patent invalidity or unenforceability, an issue that is "as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (Hand, J.).

The uncertainty stems in large part from the fact that patents do not receive anywhere near the scrutiny in the Patent and Trademark Office that they receive in subsequent court challenges. PTO proceedings are conducted *ex parte*, and the PTO is simply overwhelmed: "With yearly application totals approximating 300,000, they arrive at a rate of about 1,000 each working day." FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, at Ch. 5 p. 4 (Oct. 2003). Examiners must act quickly on these applications: "new examiners have 25 hours, and more experienced examiners have 20 hours, to examine a biotechnology patent." *Id.* at Ch. 1 p. 34.

The circumstances are radically different when the validity or enforceability of a patent is challenged in court, where the proceedings are *inter se*, the court hears from opposing experts, and the issues generally receive as much time and attention as is necessary. The result is that, despite the statutory presumption of validity, 35 U.S.C. § 282, half of all litigated patents are ultimately found to be invalid or unenforceable.

John R. Allison & Mark A: Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 206 (1998).[9]

In determining the antitrust significance of the key marketplace fact of uncertainty, the FTC was not writing on a blank slate. It is unlawful for a firm to pay a current or potential competitor to exit or stay out of the market. *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48-49 (1990).[10] It is equally unlawful to pay to eliminate *uncertain* competition:

> [T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.

XII Herbert Hovenkamp, ANTITRUST LAW ¶ 2030b at 175 (1999). For example, assume that A and B are competitors and A tells B that there is a 30% chance that A is going to lower her price

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9. As a matter of public policy, there is not necessarily any reason to be alarmed at the disparity between a harried patent examiner's and a court's view of the validity of a patent. With the notable exceptions of pharmaceutical and chemical patents, the vast majority of issued patents have little economic significance. So it is efficient and appropriate to have a patent process consisting of initial issuance based on a less-than-searching review, followed by a careful judicial review of the comparatively few patents that have genuine economic significance. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U.L. Rev. 1495 (2001). What is not good policy -- what makes no sense at all -- is to adopt an antitrust rule that would permit patentees who have gotten only half-way through this process to declare victory and then pay their would-be competitors to respect that "victory."

10. Often the conspirators agree that each of them will be allocated a particular territory, and the consideration for the agreement is the mutual promise not to compete in the other's territory. But the antitrust analysis does not change merely because, as here, only one competitor is allocated a territory and the consideration is cash rather than a promise. *See Addyston Pipe & Steel*, 175 U.S. at 241; *see also Garot Anderson Agencies, Inc. v. Blue Cross & Blue Shield United*, 1993 U.S. Dist. LEXIS 3446, at *38-39, 1993-1 Trade Cas. ¶ 70,235 (N.D. Ill. Feb. 26, 1993) (rejecting argument that agreement was not market allocation because only one defendant received a market).

next week. It is clearly unlawful for B to pay A to refrain from lowering her price. If C tells D that there is a 30% chance that C will enter into D's geographic market, it is clearly unlawful for D to pay C not to enter. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001 (en banc) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979) (unlawful to agree to suppress a product of which only a prototype had been made); *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 698 (D. Md. 2000) (finding evidence sufficient to support a finding that exclusive contract was unlawful even though causation theory required showing "that Plaintiff would have successfully secured a manufacturing facility, obtained FDA approval, developed the [product] in commercial quantities, and marketed the product during the relevant timeframe"). Of course, in order to recover damages under Section 4 of the Clayton Act, private plaintiffs are required to show that, absent the unlawful conduct, the competition would in fact have occurred. But no such additional showing was required in this FTC proceeding. *See, e.g., Spiegel, Inc. v. Federal Trade Comm'n*, 494 F.2d 59, 62 (7th Cir. 1974).

The FTC had the task of applying these principles in a circumstance in which the patentee had *both* granted an early-entry license to the challenger *and* made a substantial payment to the challenger. The issue was whether the early-entry licenses resulted in less competition than would likely have occurred absent the payments, viewed from the vantage point of the time when there was uncertainty as to who would prevail in the patent litigations. The FTC knew how much competition was provided by the early-entry licenses, so the real task was to determine how much competition would likely have occurred in the absence of the payments – to determine the baseline for a competitively benign settlement agreement.

Invoking the well-established economic concept of "expected" *i.e.*, probability-adjusted, outcomes of litigation,[11] the FTC held that the proper baseline is the amount of competition that *the parties themselves* believed, *as of the time of the agreements*, was *probable*. Pet. App. 76a-77a; *see also* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003) (proper baseline is the "competition that the patentee could . . . expect *ex ante* to exclude after trial"); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 395 (Summer 2003) ("A patent settlement cannot [lawfully] lead to lower expected consumer surplus than would have arisen from ongoing litigation").

The parties' own views of the probability-adjusted outcome of litigation is an eminently sensible competitive benchmark. It takes account of the key marketplace fact that patent litigation is inherently uncertain; it focuses on the facts as of the date of the agreement; and it acknowledges that the parties themselves are best situated to assess the likely outcome of the litigation. Moreover, the alternative — an *ex post* determination of patent validity or infringement by a court as part of a subsequent antitrust claim — is both unfairly biased against a finding of antitrust liability (Pet. App. 85a-87a) and self-defeating.[12]

The competitive baseline used by the FTC is also consistent with that used by courts in determining the legality of intellectual property settlements. In *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), the Court held that, absent evidence of unduly restrictive ancillary agreements or of unlawful accumulation of market power, the parties could

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11. *See* William M. Landes, *An Economic Analysis of Courts*, 14 J. L.& ECON. 61 (1971); *see also* George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1 (1984); and Robert T. Cootner and Daniel L. Rubinfeld, *Economic Analysis of Legal Disputes*, 27 J. OF ECON. LIT. 1067 (1989).

12. Permitting any settlement of a patent challenge is efficient only to the extent that society saves the costs of the patent litigation. Society does not save those costs if they are merely deferred until the subsequent antitrust case.

lawfully settle a patent litigation over blocking patents by entering into a cross-license agreement. A settlement by way of such cross-licenses is lawful precisely because it presumably reflects "a division of royalties according to *the value attributed by the parties* to their respective patent claims. . . ." *Id.* at 171 (emphasis added); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it did not involve "purely unilateral action" but instead involved "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of pending patent application "depends on how likely the parties consider it to be that a valid patent will issue"); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 60-61 (2d Cir. 1997) (absent payment by rights holder to alleged infringer, settlement of intellectual property litigation is presumed to flow from "hard-nosed trademark negotiations" and "the result should accord with how the parties view their respective rights").

With the competitive baseline in place, the FTC turned to whether the cash payments likely reduced the amount of competition below the baseline. The FTC began by examining two economic facts. First, earlier entry gains far less profits for the generic than it loses for the brand, and consumers get the difference. Pet. App. 77a. Both parties' economic incentive, therefore, is for the brand to simply pay the generic and split the amount that earlier entry would have brought to consumers. *Id.* at 77a-78a.

Second, the FTC again relied on the economic concept of "expected" litigation outcomes: the patentee would not make a payment to the challenger unless the payment reduced competition to a level below that expected by the patentee. Likewise, when the challenger requires a payment in order to agree to the entry date offered by the patentee, that entry date must provide less competition than the challenger himself expects under litigation. Shapiro, *Antitrust Limits to Patent Settlements*, at 407-08 ("The patent holder would not pay more than avoided litigation costs unless it believed that it was

buying later entry than it expects to face through the litigation alternative"); Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, at 1759 ("The reason the patentee is willing to make this payment is precisely because the settlement will permit it to exclude competition from the market"). The FTC summarized the relevance of these two economic facts:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

Pet. App. 76a-77a (citations omitted).

With respect to the Schering/Upsher agreement, the FTC concluded, in a finding of fact entitled to judicial deference, that there was no other purpose for the cash payments. *Id.* at 140a-141a. And the economic evidence that the payments were in exchange for reduced competition was further supported by the history of the parties' negotiations and by the terms of the agreement itself. *Id.* at 93a-107a. With respect to the Schering/ESI agreement, the defendant offered no other explanation for the payment, and, again, the economic evidence was supported by the express terms of the agreement. *Id.* at 142a-145a.

The FTC's decision concerning the proper competitive baseline was supported by caselaw and the application of standard economic principles to the real marketplace facts. Its conclusion that Schering's payments likely reduced competition below that baseline was supported by economics, the negotiation histories, the terms of the agreements, and the absence of alternative explanations.

ARGUMENT

I. THE COURT SHOULD GRANT REVIEW IN ORDER TO CORRECT THE COURT OF APPEALS' FUNDAMENTAL ERRORS OF LAW.

The Court should grant review in this case because the FTC's analysis was fundamentally sound and the Court of Appeals panel committed substantial legal error in reversing it. These considerations support the grant of review on the unique facts of this case because, through the workings of 15 U.S.C. § 45(c), the panel's erroneous decision would disable the FTC from enforcing the antitrust law against agreements that threaten enormous harm to consumers.

That the Court of Appeals panel committed fundamental error is shown, first, by the fact that the panel seems literally not to have understood the legal and economic foundation of the FTC's decision:

- The panel stated that the FTC's analysis did not include "inquiry into the merit of the '743 patent litigation." Pet. App. 9a. In fact, the very core of the competitive baseline adopted by the FTC is the merits of the '743 patent litigation as viewed by the parties themselves at the time of the agreements.

- The panel noted that both Upsher and ESI demanded substantial cash payments in addition to the agreed entry dates. *Id.* at 4a, 7a. The panel seems not to appreciate that those facts — together with the fact that in both instances Schering was willing to make the demanded payments — were clear economic evidence that the parties were reducing competition to a level below the amount that they themselves otherwise expected.

- The panel derided as "arbitrary" the FTC's conclusion that payments up to the amount of saved litigation costs would not be unlawful. *Id.* at 10a. It is clear, however, that payments in the amount of saved litigation costs do not reduce expected competition. Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, at 1758 ("Even a patentee sure to win would be willing to pay a defendant a sum up to the cost of the lawsuit to end the litigation and avoid that cost").

• The panel faulted the FTC for failing to provide record evidence that, absent the payments, the parties would in fact have agreed on earlier entry. Pet. App. 30a-31a. But the economic and other evidence showed that the payments reduced the actual amount of competition under the early entry licenses below the amount that the parties themselves expected under litigation. Whether additional competition would in fact have occurred, but for the payments, is an important question of causation in private litigation challenging these agreements, but is irrelevant in an FTC administrative proceeding.[13]

Rather than contending with the FTC's legal and economic analysis, the panel simply denied, without discussion or analysis, the essential marketplace fact that drove that analysis. Invoking the statutory presumption of validity, the panel denied the fact that, at the time of the agreements, there was uncertainty as to who would win the patent litigations. *Id.* at 18a. The panel held that, "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent." *Id.* Based on this supposed ironclad "legal right to exclude"[14] the panel thus adopted as its competitive baseline the amount of competition assuming that Schering's patent was valid and infringed, *i.e.*, zero competition. The rest of the panel's analysis flowed from this fundamental error.

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13. In private cases, plaintiffs attempt to show causation by demonstrating that, but for the payments, the parties *either*: (1) would not have settled and the challenger would have won the patent litigation; or (2) would have settled with a license granting earlier entry (or a lower royalty rate).

14. The panel disregarded this Court's frequent admonition that "the word 'right' is one of the most deceptive of pitfalls; it is so easy to slip from a qualified meaning in the premise to an unqualified one in the conclusion. Most rights are qualified." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985), quoting *Lorain Journal Co. v. United States*, 342 U.S. 143, 155 (1951), which quotes *American Bank & Trust Co. v. Federal Reserve Bank*, 256 U.S. 350, 358 (1921).

The panel's decision was deeply flawed even assuming that its antitrust analysis should, or could rationally, be based on legal presumptions regarding infringement or validity. The panel was wrong as to who has the burden of proving both infringement and validity. As to infringement – the central issue in both of the patent litigations – it is hornbook law that the patentee, not the challenger, bears the burden of proof at all stages of the litigation. *See Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004). And the patentee also bears the burden of proof as to validity where, as here, the patentee seeks to exclude the challenger from the market without a full adjudication on the merits. *See, e.g., Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) ("at the preliminary injunction stage . . . the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity" (emphasis in original)); *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) (same). If the burden of proving validity is on a patentee who seeks a court's assistance in obtaining pre-trial exclusion of a competitor, so too should that burden be borne by a patentee who eschews a court's assistance and oversight and instead pays a competitor not to enter.

The panel's more fundamental error was in premising its antitrust analysis on a legal presumption rather than on an economic analysis of marketplace realities. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) (antitrust analysis must be based on "market facts"). The rebuttable presumption of validity that undergirds the panel's entire analysis is one small piece of a larger patent *system* in which patents are issued *ex parte* and are subject to plenary review in the courts – courts that find more than half of all litigated patents to be invalid. A party that has been issued a patent by the PTO but has not yet succeeded in court is not nearly even halfway home. In the pharmaceutical arena, Congress has not only made court review plenary, but has offered a bounty for successful generic challengers. The generics' success rate – despite the presumption relied on by the panel – is greater than 70%. The FTC's economic analysis is based on the marketplace reality as viewed by the parties

themselves, and it therefore captures the economic significance of the entire patent system, not merely one tiny aspect of it.

Moreover, there is abundant evidence that Congress never intended the rebuttable presumption to create the ironclad exclusion that the panel inferred. In the Hatch-Waxman Act, Congress granted to patentees the ability to automatically exclude generic challengers, but only for a limited period of time – 30 months. After the expiration of 30 months, the FDA is free to approve a generic drug for marketing regardless of whether patent litigation is ongoing. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Similarly, in pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, until a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

Congress' understanding that patents are not ironclad, and that exclusion payment agreements are anticompetitive, was made perfectly clear in the hearings leading up to the recently enacted settlement-reporting legislation.[15] *See, e.g.*, 148 CONG. REC. S7566 (daily ed. July 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type of reverse payment collusive arrangements appalling"); 146 CONG. REC. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) ("requir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC . . . [will] ensure that existing antitrust and drug approval laws are enforced to the letter"); 147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) (remarks of Sen. Leahy) (legislation is intended to give to the FTC "the information they need to prevent manufacturers of patented drugs – often brand-name drugs – from simply paying generic drug companies to keep lower-cost products off the market").

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15. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Congress went out of its way to commend the FTC for its work in uncovering and prosecuting exclusion payment cases, including this one. *See, e.g.*, 148 CONG. REC. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws"); 148 CONG. REC. S7460 (daily ed. July 29, 2002) (remarks of Sen. Hatch) ("We ought to pay attention to the experts at the FTC and elsewhere who have spent so much time on this issue"); 146 CONG. REC. S7908-01 (daily ed. July 27, 2000) (remarks of Sen. Leahy) (congratulating the FTC for "instantly lower[ing] the boom on the companies").

Far from being consistent with Congress' intent, the panel's decision appears to be animated by an express antipathy to Congress' decision to encourage challenges to pharmaceutical patents. *See* Pet. App. 31a. Noting the Hatch-Waxman Act's patent-challenge incentives, the panel states with apparent alarm that, "This statutory scheme could then cost Schering its patent." *Id.* That alarm prompted the panel to conclude that Schering should be permitted to make exclusion payments in order to "realize[] the full potential of its infringement suit – a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future." *Id.* Permitting payments to terminate patent challenges is not a proper judicial response to Congress' decision to encourage those challenges.

The panel's related concern regarding the "caustic environment of patent litigation" and its costs (*id.* at 33a) also misses the mark. The panel failed to appreciate "the importance to the public at large of resolving questions of patent validity" so that society does not "grant monopoly privileges to the holders of invalid patents." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993). And while patent litigation is costly, the FTC permitted payments up to the amount of saved litigation costs; therefore, by definition, exclusion payments found unlawful under the FTC's analysis would result in lost consumer welfare greatly disproportionate to the relatively modest costs of patent litigation. Herbert

Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 717 (2004).

The panel also asserts that the FTC's analysis would render all patent settlements unlawful because they all involve either explicit or "implicit" consideration flowing from the patentee to the challenger. Pet. App. 32a. This is plain error. Absent an exclusion payment, a settlement by means of licensed entry (*without* any exclusion payment) is clearly not unlawful under the FTC's analysis. The baseline for a competitively benign settlement is the amount of competition expected by the parties themselves, and absent an exclusion payment, the terms of a license agreement – the entry date and the royalty rate – will reflect the parties' respective views of the strength of the patent claim. The panel's example of "implicit consideration" – the patentee's waiver of a damage claim against a challenger that has entered the market before the conclusion of patent litigation (*id.*) – is simply a species of license (*i.e.*, a retrospective, rather than a prospective, license.)

Finally, the panel's assertion that prohibiting exclusion payments would "reduce the incentive to challenge patents" (*id.* at. 33a) is illogical. Consumers are helped not by patent challenges, but by *successful* patent challenges, *i.e.*, challenges that result in generic entry through either prevailing in the patent litigation or obtaining a license. Payments in exchange for exclusion result in more exclusion, not more entry.

II. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE A CONFLICT BETWEEN THE CIRCUITS.

The Court of Appeals panel and the FTC differed sharply over the proper competitive baseline. Relying on the rebuttable presumption of validity, the panel's baseline is the amount of competition assuming that the patent is valid and infringed. Relying on marketplace reality, the FTC's baseline is the amount of competition expected by the parties themselves. The Court of Appeals for the Sixth Circuit has also ruled on this issue and has adopted the same competitive baseline used

by the FTC. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S. Ct. 307 (2004).

In *Cardizem* the patentee paid the challenger to stay out of the market pending resolution of the patent litigation (the automatic 30-month stay had expired). Relying on marketplace realities rather than a presumption of validity, the Court held that a brand manufacturer's patent does not create an "'impenetrable' legal impediment [to the generic challenger's] production and sale of its FDA-approved generic product." *Id.* at 914. Defendants' plea to adopt a baseline based on the rebuttable presumption of validity crashed headlong into economic reality: if the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude a generic competitor from the market, then the brand manufacturer "would not have paid [the generic competitor] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. The patentee's allegations of infringement merely created in the generic challenger a "fear of damages in the patent infringement litigation," *id.* at 911, a fear that *may* or *may not* have prompted the challenger, acting "unilaterally, and legally [to refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 915. The patentee's payments gave it something that the patent law did not — "the Agreement *guaranteed* to [the brand manufacturer] that its only potential competitor at that time . . . would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval." *Id.* at 907 (emphasis added); *see also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (agreement caused antitrust injury because "HMRI's [exclusion payments] were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic").

Under the Eleventh Circuit's ruling here, the antitrust laws are apparently powerless to police such exclusion agreements. Pet. App. 16a ("neither the rule of reason nor the *per se* analysis is appropriate in this context"). The Sixth Circuit reached

exactly the opposite conclusion, holding that exclusion payment settlements are *per se* unlawful. *In re Cardizem*, 332 F.3d at 900. In that Court's words, "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908.

The split between the Sixth and Eleventh Circuits is fundamental and stark. The Sixth Circuit's analysis is closely akin to that of the FTC, but that Circuit Court would make the further decision that such payments are so unlikely to ever have any procompetitive benefits that they should be condemned as *per se* unlawful. Review by this Court is necessary to ensure that the Eleventh Circuit's ruling – starkly at odds with that of another Circuit – does not dictate FTC enforcement policy on this important issue.

CONCLUSION

For the foregoing reasons, NACDS respectfully submits that this Court should grant certiorari to correct the Court of Appeal's fundamental errors and to resolve an intolerable conflict between two Circuits.

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In The
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *ET AL.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

MOTION OF THE PUBLIC PATENT FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF OF *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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MOTION OF THE PUBLIC PATENT FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Public Patent Foundation, Inc. ("PUBPAT") respectfully moves this Court to grant it leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari. Counsel for Petitioner has consented to the filing of this brief, counsel for one of the Respondents, Upsher-Smith Laboratories, Inc., has withheld consent, and counsel for the other Respondent, Schering-Plough Corporation, did not respond to a request for consent.

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public's otherwise unrepresented interests in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

PUBPAT has argued for sound patent policy before the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified wrongly

issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has significant experience in determining the exclusionary power of patents, as such an exercise is a fundamental part of each of its core activities.

Accordingly, PUBPAT respectfully requests that the Court grant leave to file the attached brief as *amicus curiae*.

Respectfully submitted,

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September 30, 2005

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INTEREST OF THE *AMICUS CURIAE*

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public's otherwise unrepresented interests in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy.[1] PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

PUBPAT has argued for sound patent policy before the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified wrongly issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than *amicus curiae* and its counsel made a monetary contribution to the preparation or submission of this brief.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has significant experience in determining the exclusionary power of patents, as such an exercise is a fundamental part of each of its core activities.

SUMMARY OF ARGUMENT

The Court of Appeals in this case made the erroneous assumption that the exclusionary power of a patent is always measured by its full statutory term. Not only is that assumption unsupported by empirical analysis of patents generally, which shows that only about one half of all asserted patents have any exclusionary power whatsoever, such assumption is categorically contradicted when a patentee and accused infringer agree on a date prior to the patent's expiration at which time the alleged infringer can,

without compensation or consequence, freely sell its product. In those circumstances, the exclusionary power of the patent, with respect to *that* product, is measured by the agreed to pre-expiration free-entry date, because such date is, in effect, a specifically tailored patent expiration date vis-à-vis that product.

If an accused infringer is given consideration in addition to a pre-expiration free-entry date, then the exclusionary power of the patent with respect to the accused infringer's product is equivalent to some date prior to the agreed-to pre-expiration free-entry date, because the extra consideration, in the absence of any other explanation, is in exchange for additional delay in entry. The Court of Appeals ignored this simple truth in this case and, in effect, promulgated a virtual exemption from antitrust law for any agreement that involves a patent. Such an exemption conflicts with this Court's precedents and with sound legal and economic theory.

Further, the Court of Appeals' unwillingness to apply sound antitrust principles for fear that such may deter pro-competitive patent settlements is based on unsound circular reasoning. By definition, application of sound antitrust principles can only deter conduct that has an anti-competitive effect. More specifically with respect to this case, deterring anti-competitive patent settlements, above and beyond protecting competition, also has the significant pro-competitive effect of encouraging more patent challenges to result in judgments.

Therefore, to protect the public from anti-competitive settlements of patent infringement litigation whereby a potential competitor is offered a share of the monopoly profits that can be maintained if it stays off the market,

this Court should grant the petition for a writ of *certiorari* and correct the mistake made by the Eleventh Circuit in this case.

REASONS FOR GRANTING THE PETITION

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, tend to give patents entirely too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over a segment of technology, patents today give their owner nothing more than, at best, a fifty-fifty chance of having any exclusionary power at all. As such, the Court of Appeals' assumption that any patent has an exclusionary power equal to its full term over any product is without merit. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), *petition for cert. filed* (Aug. 29, 2005) (No. 05-273).

If a patent holder agrees to allow the sale of a certain product prior to a patent's expiration, it is possible to determine the exclusionary power of the patent with respect to that product without resort to full-blown patent litigation. One need only look at the details of the agreement and identify what the parties negotiated the exclusionary power of the patent to be. Instead of recognizing this fundamental truth of the patent system, the Court of Appeals instead chose to blindly adopt the position that all patents are to be presumed to have total exclusionary power over any product against which they are asserted for their entire term and, thus, any settlement of a patent infringement allegation that allows an accused product to enter the market prior to the patent's expiration is exempt

from the competition laws. This conclusion is wrong and, if left undisturbed, will lead to substantial harm being caused to the American public through lessened competition and its attendant higher prices and lower choices. To be sure, this effect will be felt not only in the pharmaceutical industry, but in many other industries as well. As such, the petition for a writ of *certiorari* should be granted.

I. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT SCHERING'S PATENT DID NOT HAVE THE POWER TO EXCLUDE ALL GENERIC PRODUCTS FOR ITS ENTIRE TERM.

There is no one measure of the exclusionary power of a patent. Such is merely a relative term describing the capability of a patent to prevent the manufacture, use or sale of a specific product. The same patent can have many different exclusionary powers depending upon the characteristics of the product against which it is asserted. The exclusionary power of a patent is also affected by several other factors, including the capabilities of the party against whom it is asserted to mount an invalidity or non-infringement defense. In no case, however, can a patent be said to have the "potential" to exclude everything. At most, any given patent can only have the "potential" to exclude some defined thing or class of things.

The Court of Appeals made a critical error in this case by assuming that Schering-Plough's ("Schering") patent had an exclusionary power equivalent to its full term with respect to any generic product. This not only failed to recognize that the patent had the potential to have *no* exclusionary power with respect to those products, it was

also contrary to the significant empirical evidence regarding the exclusionary power of patents generally that is available from the literature.

While it is correct that *one* way to determine the exclusionary power of a patent with respect to a certain product is through resolution of the patent dispute by court judgment, that is not the *only* way to do so. Another effective way to determine the exclusionary power of a patent is through resolution of the dispute by agreement between the parties. It is the resolution of the dispute, not the means through which the dispute is resolved, that provides a measurement of the exclusionary power of the patent with respect to the specific product against which it has been asserted.

A. The Exclusionary Power of Patents, Generally, Is Much Less Than Their Full Term.

Patents are not as powerful as many presume. First, roughly half of all issued patents later challenged in litigation are proven to be invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998) (demonstrating that 46% of patents litigated to judgment on validity issues are held invalid); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html (detailing that, in 2003, of 201 validity decisions, the patent was found to be invalid 117 times, 58%).

Second, even if no challenge to the validity of a patent is made, accused infringers still frequently nullify any exclusionary power of the asserted patent with respect to their product by proving that their product does not

infringe the patent.[2] Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html (detailing that, in 2003, of 339 infringement decisions, the patent was found to not be infringed 255 times, 75%).

Although one comprehensive analysis performed in the late 90's determined that patent holders were successful in asserting their patents against accused infringers 58% of the time, more recent data suggests that the exclusionary power of patents in general is declining. Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (Nov. 2000); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html.

Since roughly half of all asserted patents end up having no exclusionary power whatsoever, it was improper for the Court of Appeals to assume that Schering's patent would have complete exclusionary power with respect to all generic products throughout its full term. Such an assumption was no more justified than assuming the patent will have no exclusionary power with respect to any product.

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[2] The Court of Appeals manifested an incorrect understanding of patent law when it stated that "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent." Id. at 1066. In fact, although the burden of proving a patent invalid does lie with an accused infringer, the patent holder has the burden of proving infringement. An accused infringer need not prove it does not infringe a patent in order to be outside the patent's right to exclude.

B. When a Patent Holder Allows a Product to Be Freely Sold Prior to Expiration of a Patent, the Exclusionary Power of that Patent With Respect to that Product Ends on the Date the Product Was Allowed to be Freely Sold.

Beyond general empirical analysis, there are several ways to determine what the exclusionary power of a patent is with respect to a specific product. First, and most obviously, a court can make a final determination regarding whether the patent has the power to exclude the product during the term of the patent. However, completed patent litigation is not the only way for the exclusionary power of a patent to be determined.

If a patent holder and a manufacturer of a product come to an agreement regarding the effect of a patent on that product, another way to determine the exclusionary power of the patent with respect to that product is to identify what the parties negotiated it to be in the absence of a payment from the patentee. For example, if a patent holder and alleged infringer settle a dispute between them regarding whether a specific patent has the power to exclude a specific product for the full term of the patent and the terms of that settlement allow the product to be freely sold without payment of any license fees or other consideration to the patent holder, then the exclusionary power of the patent with respect to that product ends as of the date the product is allowed to be freely sold.

The Court of Appeals seems to think that the exclusionary power of a patent can only be absolute; either zero or full term. However, such an argument fails to recognize that patent rights are fraught with inherent uncertainty and that it is economically efficient to allow patent owners

to recognize through private arrangements that their patents have the power to exclude a certain product for an amount of time less than the full term of the patent. When such a deal is struck, the exclusionary power of the patent is determined by analyzing the amount of exclusion achieved by the patent holder through the negotiation. Therefore, it is entirely possible, and actually quite frequently the case, that the exclusionary power of a patent with respect to a specific product is less than its full term.

For example, in this case the agreement between Schering and Upsher-Smith ("Upsher") implicitly had three distinct and separate economic aspects. The first economic aspect of the agreement was that Schering permitted Upsher to sell its generic K-Dur product prior to the asserted patent's expiration date without any requirement that Upsher make any payment or give any consideration to Schering other than a promise to abstain from selling the generic K-Dur product prior to that date. That agreed-to date of entry, referred to herein as T, is the most precise measure of the asserted patent's exclusionary power with respect to Upsher's product, as that was a date negotiated by parties who were, at the time of negotiation, adversaries regarding the patent's power to exclude the generic K-Dur product. In effect, T was a specifically tailored expiration date for the patent with respect to Upsher's product.

The second economic aspect of the agreement was that Schering paid Upsher some amount less than $60M for an additional promise to not sell generic K-Dur between the specifically tailored patent expiration date, T, and September 2001. This additional delay was not within the exclusionary power of the patent. Rather, it began on the day the exclusionary power of the patent ended and

extended the total amount of time Upsher delayed its sale of the generic K-Dur product.

Had Schering not paid Upsher for any additional delay, then T would be properly identified as being September 2001, or, had Upsher instead paid Schering consideration for Schering's allowance of the generic K-Dur product to be sold prior to the patent's expiration, then T would have been some date after September 2001. But, since Schering compensated Upsher for its delay with a combination of cash and a waiver of the exclusionary power of the patent, only a portion of the delay can be attributed to the patent's exclusionary power. This is why T must have been, under the terms of this agreement, some date prior to September 2001.

The final aspect of the agreement was that Schering paid Upsher some amount less than $60M for a license to Niacor-SR. The combination of the amount paid to Upsher for the additional delay and the amount paid for the license to Niacor-SR equaled the total $60M under the agreement. Set forth below in Figure 1 is a chart identifying these three aspects of the agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	Consideration Given by Schering	Consideration Given by Upsher
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date T (T is before Sept. 2001)	Promise to Not Produce Generic K-Dur Before Date T
2. Additional Exclusion	$ X (where $0 < X < $60M)	Promise to Not Produce Generic K-Dur Between Date T and September 2001
3. Niacor-SR License	$ Y (where Y = $60M – X)	License to Niacor-SR

FIGURE 1: Economic Aspects of Schering – Upsher Settlement Agreement

Admittedly, the negotiations and text of the agreement obfuscated these economic aspects. Instead of delineating each economic aspect and dealing with them separately, Respondents combined the considerations that were of like form. The consideration given by Schering for the second and third aspect of the agreement was cash, and therefore they were merged. The consideration given by Upsher for the first and second aspect of the agreement was combined into a single promise to not sell generic K-Dur prior to September 2001. Set forth below in Figure 2 is the same chart as set forth above in Figure 1, except that the considerations merged through the text of the agreement are shown as being merged in the chart.

<table>
<tr><th>Aspect</th><th>Consideration Given by Schering</th><th>Consideration Given by Upsher</th></tr>
<tr><td>1. Exclusionary Power of Schering's Patent</td><td>Promise to Not Assert Patent Against Generic K-Dur after Date T
(T is before Sept. 2001)</td><td rowspan="2">Promise to Not Produce Generic K-Dur Before September 2001</td></tr>
<tr><td>2. Additional Exclusion</td><td rowspan="2">$60M</td></tr>
<tr><td>3. Niacor-SR License</td><td>License to Niacor-SR</td></tr>
</table>

FIGURE 2: Economic Aspects of Schering – Upsher Settlement Agreement as Obfuscated by the Agreement Provisions

This merging of like-consideration is understandable, as it is easier to negotiate and draft two forms of consideration flowing from each party to the other, rather than three. However, that does not change the economic realities of the deal. Since a portion of Upsher's delay was compensated for by part of Schering's $60M, only the remaining portion of Upsher's delay was due to the power of the patent to exclude generic K-Dur. Therefore, the exclusionary power of the patent in this case with respect to Upsher's generic product was determined by the parties, whether they realized it or not at the time, to be some date prior to September 2001.

Although this is not a precise determination of the exclusionary effect of the patent, resolution of antitrust issues relating to the exclusionary power of a patent does not necessarily require a precise determination. As in this case,

antitrust analysis can be appropriately applied merely by identifying the bounds of the exclusionary effect of a patent. Therefore, it is sufficient to recognize that the parties determined, through their negotiations, that Schering's patent did not have the power to exclude Upsher's generic K-Dur product after some date prior to September 2001.

Similarly, the exclusionary effect of Schering's patent with respect to ESI Lederle's ("ESI") generic product can be determined by reviewing the Schering - ESI agreement, which is easier to analyze because it did not include the third aspect present in the Schering – Upsher agreement. In the Schering – ESI agreement, Schering allowed the ESI generic product to enter the market prior to expiration of its patent and also paid ESI $10M above and beyond its litigation costs. Since there was no other justification for that additional payment, it could only have been in exchange for additional delay of entry of ESI's generic product into the market. Therefore, the parties determined, through their agreement, that Schering's patent did not have the power to exclude ESI's generic product after some date prior to January 1, 2004, referred to herein as S. Set forth below in Figure 3 is a chart identifying these aspects of the Schering – ESI agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	Consideration Given by Schering	Consideration Given by ESI
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date S (S is before January 1, 2004)	Promise to Not Produce Generic K-Dur before Date S
2. Additional Exclusion	$10M	Promise to Not Produce Generic K-Dur Between Date S and January 2004

FIGURE 3: Economic Aspects of Schering – ESI Settlement Agreement

The Court of Appeals failure to adopt this reasoning led it to make the erroneous decision that any settlement of patent litigation is pro-competitive so long as the accused infringing product is allowed to enter the market any time before expiration of the asserted patent. This decision, if left uncorrected, will cause significant harm to the American people by permitting anti-competitive settlements of patent infringement litigation whereby potential competitors, instead of competing, take a share of the monopoly profits that can be maintained if they stay off the market. Unquestionably, such agreements are very good for the parties, and perhaps even the court system, which will have the burden placed on it lessened by the termination of patent infringement cases, but it is also just as clear to see how such agreements spell nothing but disaster for our competition-based economy and the American consumer.

II. THE COURT OF APPEALS IGNORED THIS COURT'S PRECEDENT BY EXEMPTING A SIGNIFICANT PORTION OF PATENT SETTLEMENTS FROM ANTITRUST LAW.

This Court has recognized that discouraging anticompetitive settlements of patent infringement cases has, in itself, a pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. *See Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfng. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Similarly, accused infringers who do not raise invalidity challenges to an asserted patent, but instead raise substantial noninfringement defenses also aid competition because their efforts lead to a judicial opinion declaring the patent's metes and bounds, on which the public may rely. Determining the true scope of a patent is accomplished by the courts through a process called claim construction, which is often difficult, as evidenced by the fact that the U.S. Court of Appeals for the Federal Circuit reverses over 30% of district court claim constructions. *See*

Christian Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 Berkeley Tech. L.J. 1075 (2001); *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 Harv. J.L. & Tech. 1 (2001). As such, a party that litigates the scope of a patent through the stage of claim construction aids the public in determining what the patent covers and, more importantly, what it does not. These significant pro-competitive effects that result from the discouragement of anti-competitive settlements went unrecognized by the Court of Appeals in this case.

Further, the Court of Appeals failed to recognize that application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have been able to circumvent the pro-competitive intent of Hatch-Waxman because it is "littered with loopholes." Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001). The use of patent settlement agreements to fashion a sharing of monopoly profits made by one of them instead of competing with one another in the marketplace, such as occurred in this case, is but one example of how pharmaceutical companies are attempting to circumvent Hatch-Waxman. By condoning net-anticompetitive gaming of the Hatch-Waxman regime

through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

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No. 05-273

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION AND BRIEF OF REPRESENTATIVE HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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September 30, 2005

MOTION OF REPRESENTATIVE HENRY A. WAXMAN FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Representative Henry A. Waxman respectfully moves for leave to file a brief as *amicus curiae* in support of the petitioner. Counsel for respondents Schering-Plough Corporation and Upsher-Smith Laboratories, Inc., have declined to consent to the filing of the brief, necessitating the filing of this motion.

Representative Waxman is a member of the United States House of Representatives representing California's 30th Congressional District. Representative Waxman has served in the House since 1974 and is currently Ranking Minority Member of the House Committee on Government Reform, which has investigative authority over all government agencies and areas of federal policy.

Representative Waxman has long been a leader on health issues, including universal health insurance, Medicare and Medicaid coverage, tobacco, AIDS, nursing home quality standards, women's health research and reproductive rights, and the availability and cost of prescription drugs. Most significantly for purposes of this case, Representative Waxman was one of two principal named sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, more commonly referred to as the Hatch-Waxman Act. That legislation, and the policies it reflects, is directly at issue in this case. Representative Waxman was also a leading advocate of the reforms to the Hatch-Waxman Act included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Representative Waxman seeks leave to file this brief because he believes the decision of the U.S. Court of Appeals for the Eleventh Circuit in this case stands as a significant obstacle to the fulfillment of the important public policies

embodied in the Hatch-Waxman Act and its 2003 amendments, both of which sought to speed the introduction of generic competitors to name-brand drugs, not to facilitate anti-competitive agreements between pharmaceutical companies to keep generics off the market. Representative Waxman seeks to provide the Court with additional information about the policies underlying these important pieces of legislation to assist it in appreciating the significance of this case.

Representative Waxman therefore respectfully asks that he be granted leave to file the accompanying brief as *amicus curiae* in support of the petitioner.

Respectfully submitted,

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September 30, 2005

QUESTION PRESENTED

Whether the Eleventh Circuit's approval of anti-competitive settlement agreements between generic and name-brand drug manufacturers can be squared with the policies of the Hatch-Waxman Act and its 2003 amendments.

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149 Cong. Rec. S8187 (June 19, 2003) (statement of Sen. Kohl) 3

149 Cong. Rec. S8190 (June 19, 2003) (statement of Sen. McCain) 6

149 Cong. Rec. S8193 (June 19, 2003) (statement of Sen. Gregg) 6, 9

149 Cong. Rec. S8194 (June 19, 2003) (statement of Sen. Collins) 9

Other:

Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002), at www.ftc.gov/os/2002/07/genericdrugstudy.pdf 2

Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* (Aug. 2005), at www.gao.gov/new.items/d05779.pdf 2, 3

INTEREST OF *AMICUS CURIAE*

As set forth in detail in the accompanying motion for leave to file this brief, Representative Henry A. Waxman has an interest in filing this brief as *amicus curiae* because the decision of the Eleventh Circuit in this case significantly distorts, and stands as an obstacle to the accomplishment of, the policies underlying legislation that he sponsored to facilitate competition in the market for prescription drugs.[1]

REASONS FOR GRANTING THE WRIT

This Court should grant the Federal Trade Commission's petition for certiorari because of the importance of the issue it presents concerning the Commission's authority to take action against anti-competitive agreements between brand-name and generic drug manufacturers that result in the withholding of generic drugs from the market. Such agreements are antithetical to the policies behind both the Hatch-Waxman Act and its 2003 amendments, which were designed to speed the introduction of generic competitors to brand-name drugs. In concluding that settlement agreements under which generic manufacturers are paid to keep their drugs off the market have pro-competitive justifications, the Eleventh Circuit turned the policies of the underlying federal legislation on their head. Although agreements such as those involved in this case may be an unfortunate, unintended consequence of the Hatch-Waxman Act, the Act was never intended to foster such agreements. The Act's intention was to promote competition by generic drug manufacturers, not to permit them to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market.

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[1] This brief was not authored in whole or in part by counsel for a party. No person or entity other than *amicus curiae* or his counsel made a monetary contribution to preparation or submission of this brief.

I. The Hatch-Waxman Act Was Intended to Protect Consumers Against Excessive Drug Costs by Enhancing Competition Between Name-Brand and Generic Drug Manufacturers.

The escalating cost of health care in the United States—and, in particular, of prescription drugs—is an enormous, nationwide problem. As the Government Accountability Office recently reported: "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures." Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* 1 (Aug. 2005) ("*GAO Study*"), at www.gao.gov/new.items/d05779.pdf. The GAO's analysis of the prices of 96 of the most commonly used prescription drugs showed that average prices for a one-month supply increased by 24.5% between January 2000 and December 2004. *Id.* at 7. The annual rate of increase was nearly double that of consumer prices generally over the same period. *Id.* Rising drug prices have become a matter of even more urgent concern to the federal government since the enactment in 2003 of the Medicare prescription drug benefit.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs—chemically and pharmacologically identical but lacking the brand-name—are typically much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (2002), at www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The GAO found, for example, that the price of brand-name drugs in its sample increased by 28.9% over the five-year period covered by its study, while the price of the generic drugs surveyed increased by an average of only 9.4% over the same time. *GAO Study* at 4. The annual rate of increase for the generic drugs was

significantly less than the overall inflation rate for consumer goods, which was approximately 2.5% annually, *id.* at 7, meaning that the generic drugs studied actually *declined* in price in real terms. The tremendous savings associated with generic drugs are illustrated by the fact that, in 2001, generic drug spending accounted for only $11 billion of the approximately $130 billion spent on prescription drugs, yet that $11 billion "bought 45 percent of the total prescription drugs purchased in 2001." 149 Cong. Rec. S8187 (June 19, 2003) (statement of Sen. Kohl).

The Hatch-Waxman Act, enacted in 1984, was an early attempt to address the problem of prescription drug prices by encouraging competition against brand-name drugs from generic drug manufacturers. The legislation established a procedure whereby a generic drug manufacturer could obtain accelerated FDA approval of a drug by filing an "abbreviated new drug application," or ANDA, and demonstrating the drug's equivalence to an already-approved name-brand drug. 21 U.S.C. § 355(j). Moreover, the generic manufacturer could obtain permission to begin marketing a drug within the term of an existing patent by certifying either that the patent was invalid or that it would not be infringed by manufacture of the generic. *Id.* § 355(j)(2)(A)(vii)(IV). The legislation further encouraged introduction of generic versions of patented drugs by granting the first generic manufacturer to file a challenge to a patent on a name-brand drug a 180-day period of marketing exclusivity for the generic drug, beginning on the earlier of the first day of commercial marketing, or the date of a judicial decision holding the patent on the drug to be invalid or not infringed. *Id.* § 355(j)(5)(B)(iv).

Of course, the Act did not abrogate the patent rights of manufacturers of name-brand drugs. Rather, it sought to speed resolution of disputes over the validity and scope of drug patents by requiring a company filing an ANDA to give notice to the patent-holder, and by providing a 45-day period within which the patent-holder could obtain a 30-month stay

of the FDA's approval of the ANDA if it filed a patent infringement action against the generic manufacturer. *Id.* §§ 355(j)(2)(B) & (j)(5)(B)(iii). The Act further required that any such infringement action be expedited. *Id.* § 355(j)(5)(B)(iii). Absent an infringement action, the Act directed the FDA to approve a proper ANDA within 180 days of filing, with the approval effective immediately. *Id.* § 355(j)(5)(A).

The Act contained other provisions aimed at encouraging innovation in the development of prescription drugs by granting an extended term to drug patents to take into account delays in FDA approval that otherwise could cut into the value of a patent on a drug, *see* 35 U.S.C. § 156, and by granting innovative new drugs periods of market exclusivity during which no generic drugs could be approved, *see* 21 U.S.C. §§ 355(c)(3)(D) & (j)(4)(D). The Act thus sought to achieve a careful balance between its objectives of protecting legitimate patent rights and encouraging generic competition. *See* 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman) (describing "fundamental balance of the bill").

Notwithstanding the Act's concern for legitimate patent rights, the purpose of its provisions concerning generic drugs was clear: "to make available more low cost generic drugs by establishing a generic drug approval process for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Act reflected the concern that then-existing FDA procedures, which required generic drug manufacturers to complete the lengthy procedures for new drug approval once patents protecting the name-brand drug expired, "had serious anti-competitive effects," the result of which was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984). The ANDA procedure, which speeded approval for generics that were equivalent to approved drugs, sought to combat these anti-competitive effects and to "implement the policy objective of

getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. *Id.* at 9.

But the Act's framers did not limit their efforts to permitting licensing of generic drugs only after expiration of patents on name-brand drugs; rather, they made clear their intent that "a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired," so long as it alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. By placing the burden on the patent-holder to initiate litigation and by providing only for a limited stay of FDA approval of the generic even if such litigation was sought, the drafters provided that "the FDA will approve the generic application, even if the drug is still on patent." *Id.* Moreover, the legislation's backers rejected efforts to amend it to limit FDA authority to license generic versions of patented drugs because such amendments would "substantially delay generics from getting into the market when they seek to challenge the validity of a patent." *Id.* at 10.

The ultimate goal of all of these provisions was to "provide low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman). The legislators who voted for the Act anticipated that it "will do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because it will bring about lower priced generic alternatives to brand-name drugs once the patent has expired or if there is no valid patent and the courts decide there is no valid patent in order to give that monopoly protection." *Id.* (statement of Rep. Waxman).

II. Congress Reaffirmed Its Commitment to Competition Between Generic and Name-Brand Drugs When It Passed the Medicare Drug Benefit Legislation of 2003, Which Contained New Provisions to Combat Abuses That Had Arisen Under Hatch-Waxman.

Although the Hatch-Waxman Act achieved the purpose of streamlining the approval of generic versions of brand-name drugs, two decades of experience under the Act showed that pharmaceutical companies were sometimes able to use anti-competitive devices to thwart its objective of promoting competition from generic drug manufacturers. Concerns that drug manufacturers were able to "game the system"[2] ultimately led Congress to include in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, new provisions that underscored the pro-competitive purposes of the Hatch-Waxman Act.

The concerns that led to the 2003 amendments largely involved two devices employed under the Hatch-Waxman Act to slow generic competition against drugs subject to patent. The first was abuse of the 30-month stay of FDA approval once patent infringement litigation was filed: Pharmaceutical companies, Congress learned, had been able to obtain multiple, successive 30-month stays by invoking multiple patents allegedly protecting the same drug, resulting in "basically interminable stays." 149 Cong. Rec. S8193 (June 19, 2003) (statement of Sen. Gregg).

The second device that provoked Congress's disapproval (and that has now prompted the filing of the FTC's petition for certiorari in this case) was the use of settlement agree-

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[2] 149 Cong. Rec. S8190 (June 19, 2003) (statement of Sen. McCain) (quoting testimony of former FTC Chairman Timothy Muris); *see also id.* at S8193 (statement of Sen. Gregg) ("What we saw, regrettably, under Hatch-Waxman, was there were games being played.").

ments in patent litigation, where a manufacturer of a brand-name drug paid a generic manufacturer that had filed an ANDA to withhold the generic drug from the market even after the expiration of the 30-month stay on FDA approval. A 2002 Senate Report explained the problem as follows:

> The pharmaceutical industry has been able to reap significant profits by selling vitally important drugs to all consumers, especially senior citizens. However, the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives. ....
>
> Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug. The Federal Trade Commission reports that some firms are exploiting that provision of law by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.

S. Rep. No. 107-167, at 4 (June 20, 2002).[3]

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[3] Senate Report No. 107-167 concerned legislation passed by the Senate but not the House during the 107th Congress, which contained

(*Footnote continued*)

The Senate Report went on to explain how the economics of the prescription drug market created incentives for such anti-competitive agreements:

> Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the [patent-holder] and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the [patent-holder] following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.
>
> Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the [first ANDA] and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

Id. at 10.

The same concerns about anti-competitive agreements between name-brand and generic manufacturers that were set

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provisions that were ultimately included in the Hatch-Waxman Act amendments passed by the 108th Congress as part of the 2003 Medicare drug benefit legislation. There is no separate report concerning the amendments as enacted in the 108th Congress, other than a very brief discussion in the Conference Report focusing on other issues. H. Conf. Rep. 108-391, at 835-36 (Nov. 21, 2003).

forth in the 2002 Senate Report were repeated in the 2003 floor debates surrounding the Medicare drug legislation. Senator Gregg, one of the principal sponsors of the amendments to the Hatch-Waxman Act, explained that the "games" that gave rise to the amendments included "games on the generic side where they might team up with a brand name and take advantage of the 180-day exclusivity clause and never bring the drug to market even though they had filed." 149 Cong. Rec. S8193 (June 19, 2003). Senator Collins elaborated on the problem of anti-competitive settlement agreements between name-brand and generic manufacturers:

> One case involved the producer of a heart medication which brought a lawsuit for patent and trademark infringement against the generic manufacturer in early 1996. Instead of asking the generic company to pay damages, however, the brand name manufacturer offered a settlement to pay the generic company more than $80 million in return for keeping the generic drug off the market. In the meantime, the consumers of this heart medication, which treats high blood pressure, chest pains, and heart disease, were paying about $73 a month, while the generic would have cost them only $32 a month.

Id. at S8194.

The 2003 amendments sought to further the Hatch-Waxman Act's original goals of speeding the introduction of generic drugs to the market in a number of ways. First, they altered the 30-month stay provisions to address the problem of generics being blocked by multiple, successive stays. *See* Pub. L. No. 108-173 § 1101, 117 Stat. 2448 (amending 21 U.S.C. § 355(j)). Second, they added provisions to enhance the ability of a generic manufacturer that had filed an ANDA to bring a declaratory judgment action with respect to the validity or infringement of a patent covering the brand-name drug even if the brand-name manufacturer did not itself bring an infringement action, thus expediting the elimination of

uncertainty that might otherwise inhibit marketing of the generic version. *See id.* § 1101(a)(2)(C), 117 Stat. 2450 (adding 21 U.S.C. § 355(j)(5)(C)). Third, and most importantly here, the amendments required that all agreements between brand-name and generic manufacturers concerning the marketing of drugs subject to an ANDA be submitted to the FTC and the Justice Department for review, and provided that the generic manufacturer would forfeit its 180-day exclusivity rights if, as a result of enforcement action by either the FTC or the Justice Department, such an agreement were found to violate the antitrust laws or the FTC Act. *Id.* §§ 1102, 1111-18, 117 Stat. 2458-59, 2461-64 (codified at 21 U.S.C. § 355(j)(5)(D) and 21 U.S.C. § 355 note).

By subjecting agreements of the type at issue in this case to stringent governmental scrutiny and providing an additional penalty if they were found to violate the antitrust laws, the 2003 amendments underscored that the Hatch-Waxman Act was never intended to foster such anti-competitive arrangements. Indeed, all of the 2003 amendments were designed to counter anti-competitive practices that had arisen in the years following the Act's passage and to re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers.

III. The Eleventh Circuit's Decision Undermines the Hatch-Waxman Act's Pro-Competitive Policy.

The Eleventh Circuit turned the pro-competitive policy embodied in the Hatch-Waxman Act and the 2003 amendments on its head by asserting that the provisions of the Act somehow provided a *justification* for agreements under which generic manufacturers withheld their products from the market in return for payments from brand-name drug makers. Quoting *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003), the Eleventh Circuit criticized the FTC for "neglect[ing] to understand" that "reverse payments are a natural by-product of

the Hatch Waxman Act process." 402 F.3d at 1074. The Eleventh Circuit seemed to believe that because the Act created a situation where generic drug manufacturers *could* extract settlement payments in return for keeping their products off the market, such agreements were somehow competitively justified and, indeed, endorsed by the Act.

To be sure, the Hatch-Waxman Act enhanced the bargaining position of generic manufacturers in settlement negotiations by removing regulatory barriers to their entry into the market. But the reason the Act enhanced the position of the generics was to encourage them to enter the market, *not* to authorize them to use their increased leverage to exact a share of a name-brand drug owners' monopoly profits in return for *staying out of the market*. The Eleventh Circuit confused an unintended consequence of the original legislation—its creation of incentives for anti-competitive as well as competitive behavior—with its "natural" and intended effects.

Unlike the Eleventh Circuit, other courts have recognized that opportunities for anti-competitive agreements were by no means *natural* outgrowths of the Hatch-Waxman Act's purposes, but distortions of its intended effect. Even the *Ciprofloxacin* decision relied on by the Eleventh Circuit recognized that use of the Hatch-Waxman process to delay a would-be generic competitor's entry into the market through reverse payments is an "*unintended* consequence of altering the litigation risks of patent lawsuits." *Ciprofloxacin*, 261 F. Supp. 2d at 252 (emphasis added). Similarly, the D.C. Circuit has recognized that the statutory scheme creates an "unfortunate" opportunity for the "first applicant [to] collude[] with the pioneer drug company to eliminate generic competition." *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1067, 1072 (D.C. Cir. 1998). That result, however, is "at odds with Congress's apparent purposes, in enacting [the Hatch-Waxman Act], of rewarding innovation and bringing generic drugs to market quickly. Indeed, the first applicant

could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely." *Id.* at 1072; *see also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 768 (D.N.J. 1999) (stating that "taking advantage of the exclusivity period in an anticompetitive manner" would "fal[l] squarely within what the court in *Mova* speculated would be an abuse of the statute"); *In re Cardizem CD Antitrust Litigation*, 218 F.R.D. 508, 534 (E.D. Mich. 2003) (recognizing that Congress has "worked to amend Hatch-Waxman's exclusivity provisions to curb the very abuses alleged in this action"), *aff'd in part and app. dism'd in part*, 391 F.3d 812 (6th Cir. 2004), *cert. denied sub nom. Sams v. Hoechst Aktiengesellschaft*, 125 S. Ct. 2297 (2005).

Of course, whenever a statute is designed to foster competition, it may be "natural" for industry participants to respond by agreeing *not* to compete in order to share higher monopoly profits—"natural" in the sense that industry often tends toward anti-competitive behavior. But that tendency, whether "natural" or not, does not provide a competitive justification for such agreements when they are challenged under the antitrust laws—which, after all, are designed principally to curb such tendencies—nor does it demonstrate that the anti-competitive behavior is consistent with the aims of the underlying statute. Rather, as the Fifth Circuit has noted in a different context, "actions taken to 'subvert' [a regulatory] scheme 'for anticompetitive purposes' are subject to the antitrust laws." *Woods Exploration & Producing Co. v. Aluminum Co. of America*, 438 F.2d 1286, 1303 (5th Cir.1971).

More generally, the Eleventh Circuit's decision is in tension with decisions that have recognized, outside the settlement context, that use of the Hatch-Waxman process to prevent generic competition is impermissible because it would "turn the intent of the Hatch-Waxman Act on its head" and "allow, in effect, a monopoly . . . when such rights could not be obtained through the normal patent process." *Alcon Labo-*

ratories, Inc. v. Allergan, Inc., 256 F. Supp. 2d 1080, 1089 (C.D. Cal. 2003) (criticizing brand-name manufacturer's attempt to "effectively circumvent the rationale and intent of the Hatch-Waxman Act" by bringing an action for inducing infringement against a competing generic manufacturer prior to FDA approval); *see also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003) (noting need to ensure that "the incentive structure created by the Hatch-Waxman Amendments" not "be turned on its head"), *aff'd sub nom. Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). These courts have refused to permit drug manufacturers to use the Act as a "sword" to fend off competing generic manufacturers because "[t]hat would certainly not advance the purpose of making available 'more low cost generic drugs,' and was not what Congress intended." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003).

Moreover, the Eleventh Circuit's decision significantly undermines the effect of the 2003 amendments to the Hatch-Waxman Act. The amendments were designed to enhance the federal government's authority to police anti-competitive agreements between generic and brand-name drug manufacturers and to create a significant new disincentive to such agreements: forfeiture of the 180-day exclusivity period granted to the first generic manufacturer to challenge a patent if the generic is found to have entered an agreement with a brand-name manufacturer that violates the antitrust laws. However, in enacting the provisions for FTC and DOJ review of agreements between generic and brand-name manufacturers, as well as the new forfeiture provision, Congress relied on the adequacy of *existing* principles of antitrust law to condemn agreements whereby generics withheld drugs from the market in exchange for a share of the brand-name manufacturer's monopoly profits. *See* S. Rep. No. 107-167, at 1.

The Eleventh Circuit's aggressive second-guessing of the FTC's decision about the agreements in this case, and its er-

roneous notion that settlement agreements involving payments to generics to keep their products off the market are a natural consequence of Hatch-Waxman, threatens to render the mechanism Congress created to police anti-competitive agreements toothless. Because it seems to be based on the notion that Hatch-Waxman somehow dictates application of weaker-than-normal antitrust constraints to anti-competitive agreements such as those at issue here, the Eleventh Circuit's reasoning makes it doubtful whether any FTC enforcement action in this field can survive (particularly given that drug manufacturers will generally be free to mount any challenges to FTC activity in that court). The decision below thus stands as a significant obstacle to the accomplishment of Congress's intent, in the 2003 legislation, to correct the abuses that had arisen under the Hatch-Waxman Act and shore up the Act's principal purpose of increasing competition in the prescription drug market for the benefit of consumers.

The Eleventh Circuit concluded its opinion by stating that the result it reached "reflects policy." 402 F.3d at 1076. But *whose* policy? The policy the Eleventh Circuit chose to follow was one of its own invention, not the one chosen by Congress when it enacted the Hatch-Waxman Act and its 2003 amendments. Congress's clearly stated goal was to lower drug prices by enhancing generic drug competition. The predictable result of the policy the Eleventh Circuit has chosen to substitute for that of Congress will be less competition and higher drug prices for all Americans.

CONCLUSION

For the foregoing reasons, the FTC's petition for a writ of certiorari should be granted.

Respectfully submitted,

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